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IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF WYOMING

SWEETWATER COUNTY, WYOMING, Plaintiffs, v. PURDUE PHARMA L.P.; PURDUE, PHARMA, INC.; THE PURDUE FREDERICK COMPANY, INC.; JOHNSON & JOHNSON; JANSSEN PHARMACEUTICALS, INC.; ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC. n/k/a JANSSEN PHARMACEUTICALS, INC.; JANSSEN PHARMACEUTICA INC. n/k/a JANSSEN PHARMACEUTICALS INC.; TEVA PHARMACEUTICALS USA INC.; CEPHALON, INC.; ENDO HEALTH SOLUTION INC.; ENDO PHARMACEUTICALS, INC.; ALLERGAN PLC f/k/a ACTAVIS PLC, WATSON PHARMACEUTICALS, INC. n/k/a ACTAVIS, INC.; WATSON	)	Civil Action No.: 19CV07-F

Receipt # CAS0002175
Summons ___ issued
✓ not issued

LABORATORIES, INC.; ACTAVIS, LLC,)
ACTAVIS PHARMA, INC. f/k/a WATSON)
PHARMA, INC.; INSYS THERAPEUTICS,)
INC.; MALLINCKRODT PLC,)
MALLINCKRODT, LLC; MCKESSON)
CORPORATION; CARDINAL HEALTH,)
)
INC.; AMERISOURCEBERGEN DRUG)
CORPORATION,)
)
Defendants.)

COMPLAINT AND JURY DEMAND

COMES NOW Plaintiff, Board of County Commissioners for Sweetwater County, Wyoming, ("Plaintiff"), by and through undersigned counsel, and brings this Complaint against Defendants Purdue Pharma L.P.; Purdue Pharma, Inc.; The Purdue Frederick Company, Inc.; Teva Pharmaceutical Industries, LTD.; Teva Pharmaceuticals USA, Inc.; Cephalon, Inc.; Johnson & Johnson; Janssen Pharmaceuticals, Inc.; Ortho-McNeil-Janssen Pharmaceuticals, Inc. n/k/a Janssen Pharmaceuticals, Inc.; Janssen Pharmaceutica Inc. n/k/a Janssen Pharmaceuticals, Inc.; Noramco, Inc.; Endo Health Solutions Inc.; Endo Pharmaceuticals, Inc.; Allergan plc f/k/a Actavis plc; Watson Pharmaceuticals, Inc. n/k/a Actavis, Inc.; Watson Laboratories, Inc.; Actavis, LLC; Actavis Pharma, Inc. f/k/a Watson Pharma, Inc.; Mallinckrodt plc; Mallinckrodt LLC; Insys Therapeutics, Inc.; McKesson Corporation; Cardinal Health, Inc.; AmerisourceBergen Drug Corporation (collectively "Defendants") and alleges as follows:

I. INTRODUCTION

1. Plaintiff brings this civil action to abate the hazard to public health and safety caused by the opioid epidemic, to abate the nuisance caused thereby, and to recoup monies that have been spent because of Defendants' false, deceptive and unfair marketing and/or unlawful

diversion of prescription opioids.[1] Such economic damages were foreseeable to Defendants and were sustained because of Defendants intentional and/or unlawful actions and omissions. Plaintiff does not assert product liability claims or otherwise allege that a product was defective.

2. Opioid analgesics are widely diverted and improperly used, and the widespread abuse of opioids has resulted in a national epidemic of opioid overdose deaths and addictions.[2] The opioid epidemic is "directly related to the increasingly widespread misuse of powerful opioid pain medications.[3]

3. Plaintiff brings this action against the manufacturers of prescription opioids. The manufacturers aggressively pushed highly addictive, dangerous opioids, falsely representing to doctors that patients would only rarely succumb to drug addiction. These pharmaceutical companies aggressively advertised to and persuaded doctors to prescribe highly addictive, dangerous opioids, turning patients into drug addicts for their own corporate profit. Such actions were intentional and/or unlawful.

4. Each Defendant has spent, and some continues to spend, millions of dollars on promotional activities and materials that falsely deny or trivialize the risks of opioids and overstate the benefits of opioids. As to the risks, Defendants falsely and misleadingly: (1) Downplayed the serious risk of addiction;[4] (2) promoted the concept of "pseudoaddiction," claiming that the signs of addiction should be treated with more opioids; (3) exaggerated the effectiveness of screening tools in preventing addiction; (4) claimed that opioid dependence and

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[1] As used throughout this Complaint, the term "opioid" refers to the entire family of opiate drugs including natural, synthetic and semi-synthetic opiates.

[2] See Nora D. Volkow & A. Thomas McLellan, Opioid Abuse in Chronic Pain—Misconceptions and Mitigation Strategies, 374 N. Eng. J. Med. 1253 (2016).

[3] *See* Robert M. Califf et al., *A Proactive Response to Prescription Opioid Abuse*, 374 N. Eng. J. Med. 1480 (2016).

[4] Addiction is classified as a spectrum of "substance use disorders" that range from misuse and abuse of drugs to addiction. Patients stiffer negative consequences wherever they fall on this spectrum. In this Complaint, "addiction" refers to the entire range of substance abuse disorders.

withdrawal are easily managed; (5) denied the risks of higher opioid dosages; and (6) exaggerated the effectiveness of abuse-deterrent opioid formulations to prevent abuse and addiction. Defendants also falsely touted the benefits of long-term opioid use, including its supposed ability to improve function and quality of life, even though there was no "good evidence" to support those benefits.

5. Each Defendant knew that its longstanding and ongoing misrepresentations of the risks and benefits of opioids were not supported by, or were directly contrary to, the scientific evidence. The falsity of each Defendant's misrepresentations has been confirmed by the U.S. Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC), including by the CDC in its Guideline for Prescribing Opioids for Chronic Pain, issued in 2016 and approved by the FDA (2016 CDC Guideline). On information and belief, opioid manufacturers, including Defendants Endo Pharmaceuticals, Inc. and Purdue Pharma L.P., have also entered into agreements with public entities that prohibit them from making many of the misrepresentations identified in this Complaint in other jurisdictions. Yet even now, the Defendants continue to misrepresent the risks and benefits of long-term opioid use in Wyoming, and continue to fail to correct its past misrepresentations.

6. Defendants' false and misleading statements deceived doctors and patients about the risks and benefits of opioids and convinced them that opioids were not only appropriate but necessary for the treatment of chronic pain. Defendants targeted susceptible prescribers like family doctors as well as vulnerable patient populations like the elderly and veterans. And they tainted the sources that doctors and patients relied upon for guidance, including treatment guidelines, continuing medical education programs, medical conferences and seminars, and scientific articles. As a result, Defendants successfully transformed the way doctors treat chronic

pain, opening the floodgates of opioid prescribing and use. Opioids are now the most prescribed class of drugs; they generated $11 billion in revenue for drug companies in 2014 alone. This explosion in opioid prescriptions and use has padded Defendants' profit margins at the expense of chronic pain patients. As the CDC recently recognized, "for the vast majority of [those] patients, the known, serious, and too-often fatal risks far outweigh the unproven and transient benefits."[5]

7. The explosion in opioid prescriptions and use caused by Defendants has led to a public health crisis in Sweetwater County, Wyoming, which faces skyrocketing opioid addiction and opioid-related overdoses and deaths as well as devastating social and economic consequences. This public health crisis is a public nuisance because it "is injurious to health" and interferes "with the comfortable enjoyment of life and property" and because it affects "entire communit[ies]" and "neighborhood[s]" and "any considerable number of persons". As the FDA acknowledged in February 2016, "[t]hings are getting worse, not better, with the epidemic of opioid misuse, abuse and dependence."

8. Each Defendant's deceptive marketing and distribution scheme has precipitated this public health crisis in Wyoming, including Sweetwater County, by dramatically increasing opioid prescriptions and use. Opioid prescriptions in Wyoming far exceed the national average.[6] An oversupply of prescription opioids has provided a source for illicit use or sale of opioids (the supply), while the widespread use of opioids has created a population of patients physically and psychologically dependent on them (the demand). And when those patients can no longer afford or legitimately obtain opioids, they often turn to the street to buy prescription opioids or even heroin.

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[5] Thomas R. Frieden et al., *Reducing the Risks of Relief — The CDC Opioid-Prescribing Guideline,* 374 New Eng. J. Med. 1501-1504 (2016).

[6] amfAR Opioid and Health Indicators, Wyoming (2018).

9. The effects of Defendants' deceptive marketing and distribution scheme has further impacted Plaintiff Sweetwater County (hereinafter "Sweetwater County" or "Plaintiff") in a foreseeable way such that Plaintiff must devote increased resources to the burden of the addicted homeless who commit drug and property crimes, to feed their addiction. For example, tax dollars are required to maintain public safety of places where the addicted homeless attempt to congregate, including city parks, schools and public lands. Tax dollars are required to fight the injections disease brought by the addicted and particularly the addicted homeless. Hepatitis B and C,[7] HIV, sexually transmitted disease and methicillin-resistant Staphylococcus aureus (MRSA) have been demonstrated to be spread by opioid abuse.

10. The role of Defendants' deceptive marketing and distribution scheme in causing this public health crisis has become well-recognized in recent years. In her May 2014 testimony to the Senate Caucus on International Narcotics Control on behalf of the National Institutes of Health (NIH), Dr. Nora Volkow explained that "aggressive marketing by pharmaceutical companies" is "likely to have contributed to the severity of the current prescription drug abuse problem."[8] And in August 2016, the former U.S. Surgeon General expressly connected the "urgent health crisis" to "heavy marketing of opioids to doctors . . . . [m]any of [whom] were even taught — incorrectly — that opioids are not addictive when prescribed for legitimate pain."[9] Wyoming doctors, addiction treatment specialists, and law enforcement and public

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[7] Wyoming ranked first in estimated acute Hepatitis C cases per 100,000 in 2018. amfAR Opioid Health Indicators, Wyoming (2018).

[8] America's Addiction to Opioids: Heroin and Prescription Drug Abuse, available at: https://www.drugabuse.gov/about-nida/legislative-activities/testimony-tocongress/2016/americas-addiction-to-opioicls-heroin-prescription-drug-abuse [as of July 7. 2017].

[9] Vivek H. Murthy, *Letter from the Surgeon General,* August 2016, available at: http://turnthetiderx.org.

health officials confirm that prescription opioids lawfully prescribed by doctors have fueled this epidemic.

11. Absent each Defendant's deceptive marketing scheme and improper distribution, opioid prescribing, use, misuse, abuse, and addiction would not have become so widespread, and the opioid epidemic that now exists would have been averted or much less severe.

12. By falsely downplaying the risks and exaggerating the benefits of long-term opioid use through their deceptive marketing claims, and by improperly distributing prescription opioids as set forth herein, Defendants have not only engaged in false advertising and unfair competition, they have also created or assisted in the creation of a public nuisance. Although this Complaint focuses on Defendants' misconduct during the applicable limitations period and only references their earlier misconduct, every act of malfeasance committed by each Defendant since the late 1990s as part of its deceptive marketing and distribution scheme subjects that Defendant to liability for public nuisance because there is no statute of limitation for a public nuisance claim.

13. By this action, Sweetwater County further seeks to recoup tax dollars already spent for the consequences of Defendants' wrongful conduct in causing the opioid epidemic and crisis and its impact on the city and community, and to abate the opioid nuisance so Sweetwater County will not be required to spend further taxpayer dollars on the epidemic and crisis wrought by Defendants' wrongful conduct as alleged herein.

II. PARTIES

A. PLAINTIFF

14. Plaintiff is authorized to bring this action pursuant to Wyo. Stat. § 18-2-101 (a)(i). The distribution and diversion of opioids into Wyoming ("the State"), and into Sweetwater

County ("the County") and surrounding areas (collectively, "Plaintiff's Community"), created the foreseeable opioid crisis for which Plaintiff seeks relief.

15. Opioid abuse, addiction, morbidity and mortality has created a serious public health and safety crisis, and is a public nuisance, in Sweetwater County, Wyoming. The diversion of legally produced controlled substances into the illicit market causes or contributes to this public nuisance.

16. Through this action, Plaintiff does not seek to limit the ability of doctors in Wyoming to prescribe opioids, nor does Plaintiff request that this Court weigh the risks and benefits of long-term opioid use. Rather, Plaintiff seeks an order requiring Defendants to cease their unlawful promotion and distribution of opioids, to correct their misrepresentations, and to abate the public nuisance they have created. To redress and punish Defendants' previous and current violations of law that cause and continue to cause harm to the Sweetwater County and its residents, Plaintiff seeks a judgment requiring Defendants to pay civil penalties, restitution, and any fees or costs permitted under law.

17. As a direct and foreseeable result of Defendants' misconduct, Plaintiff has sustained all economic damages alleged herein. Defendants' conduct has caused a significant financial burden for which the Plaintiff seeks relief. Categories of past and continuing sustained damages include, inter alia,: (1) costs for providing medical care, additional therapeutic, and prescription drug purchases, and other treatments for patients suffering from opioid-related addiction or disease, including overdoses and deaths; (2) costs for providing treatment, counseling, and rehabilitation services; (3) costs for providing treatment of infants born with opioid-related medical conditions; (4) costs associated with law enforcement, incarceration, and public safety relating to the opioid epidemic; (5) and costs associated with providing care for

children whose parents suffer from opioid-related disability or incapacitation. These damages have been suffered, and continue to be suffered, by the Plaintiff.

18. Plaintiff also seeks the means to address and eliminate the opioid epidemic created by Defendants' wrongful and/or unlawful conduct.

19. Plaintiff has standing to recover damages incurred as a result of Defendants' actions and omissions. Plaintiff has standing to bring all claims pled herein, including, inter alia, to bring claims under the federal RICO statute, pursuant to 18 U.S.C. § 1961(3) ("persons" include entities which can hold legal title to property) and 18 U.S.C. § 1964 ("persons" have standing).

B. DEFENDANTS

1. Manufacturer Defendants

20. The Manufacturer Defendants are defined below. At all relevant times, the Manufacturer Defendants have packaged, distributed, supplied, sold, placed into the stream of commerce, labeled, described, marketed, advertised, promoted and purported to warn or purported to inform prescribers and users regarding the benefits and risks associated with the use of the prescription opioid drugs. Defendants, at all times, have manufactured and sold prescription opioids without fulfilling their legal duty to prevent diversion and report suspicious orders.

21. PURDUE PHARMA L.P. is a limited partnership organized under the laws of Delaware. PURDUE PHARMA INC. is a New York corporation with its principal place of business in Stamford, Connecticut, and THE PURDUE FREDERICK COMPANY is a Delaware corporation with its principal place of business in Stamford, Connecticut (collectively, "Purdue").

22. On information and belief, Purdue manufactures, promotes, sells, and distributes opioids such as OxyContin, MS Contin, Dilaudid/Dilaudid HP, Butrans, Hysingla ER, and Targiniq ER in the United States. OxyContin is Purdue's best-selling opioid. Since 2009, Purdue's annual nationwide sales of OxyContin have fluctuated between $2.47 billion and $2.99 billion, up four-fold from its 2006 sales of $800 million. OxyContin constitutes roughly 30% of the entire market for analgesic drugs (painkillers).

23. CEPHALON, INC. is a Delaware corporation with its principal place of business in Frazer, Pennsylvania. TEVA PHARMACEUTICAL INDUSTRIES, LTD. ("Teva Ltd.") is an Israeli corporation with its principal place of business in Petah Tikva, Israel. In 2011, Teva Ltd. acquired Cephalon, Inc. TEVA PHARMACEUTICALS USA, INC. ("Teva USA") is a Delaware corporation and is a wholly owned subsidiary of Teva Ltd in Pennsylvania. Teva USA acquired Cephalon in October 2011.

24. On information and belief, Cephalon, Inc. manufactures, promotes, sells, and distributes opioids such as Actiq and Fentora in the United States. Actiq has been approved by the FDA only for the "management of breakthrough cancer pain in patients 16 years and older with malignancies who are already receiving and who are tolerant to around-the-clock opioid therapy for the underlying persistent cancer pain."[10] Fentora has been approved by the FDA only for the "management of breakthrough pain in cancer patients 18 years of age and older who are already receiving and who are tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain."[11] In 2008, Cephalon pled guilty to a criminal violation of the Federal

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[10] *Highlights of Prescribing Information, ACTIQ® (fentanyl citrate) oral transmucosal lozenge, CII* (2009), https://www.accessdata.fda.gov/drugsatfda_docs/label/2009/020747s030lbl.pdf.

[11] *Highlights of Prescribing Information, FENTORA® (fentanyl citrate) buccal tablet, CII* (2011), https://www.accessdata.fda.gov/drugsatfda_docs/label/2012/021947s015lbl.pdf.

Food, Drug and Cosmetic Act for its misleading promotion of Actiq and two other drugs, and agreed to pay $425 million.[12]

25. Teva Ltd., Teva USA, and Cephalon, Inc. work together closely to market and sell Cephalon products in the United States. Teva Ltd. conducts all sales and marketing activities for Cephalon in the United States through Teva USA and has done so since its October 2011 acquisition of Cephalon. Teva Ltd. and Teva USA hold out Actiq and Fentora as Teva products to the public. Teva USA sells all former Cephalon branded products through its "specialty medicines" division. The FDA-approved prescribing information and medication guide, which is distributed with Cephalon opioids, discloses that the guide was submitted by Teva USA, and directs physicians to contact Teva USA to report adverse events.

26. Cephalon's promotional websites, including those for Actiq and Fentora, display Teva Ltd.'s logo.[13] Teva Ltd.'s financial reports list Cephalon's and Teva USA's sales as its own, and its year-end report for 2012 – the year immediately following the Cephalon acquisition – attributed a 22% increase in its specialty medicine sales to "the inclusion of a full year of Cephalon's specialty sales," including inter alia sales of Fentora®.[14] Through interrelated operations like these, Teva Ltd. operates in the United States through its subsidiaries Cephalon and Teva USA. The United States is the largest of Teva Ltd.'s global markets, representing 53% of its global revenue in 2015, and, were it not for the existence of Teva USA and Cephalon, Inc., Teva Ltd. would conduct those companies' business in the United States itself. Upon information

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[12] Press Release, U.S. Dep't of Justice, Biopharmaceutical Company, Cephalon, to Pay $425 Million & Enter Plea to Resolve Allegations of Off-Label Marketing (Sept. 29, 2008), https://www.justice.gov/archive/opa/pr/2008/September/08-civ-860.html.

[13] *See* ACTIQ, http://www.actiq.com/ (displaying Teva logo at bottom-left) (last visited December 18, 2018).

[14] Teva Ltd., Annual Report (Form 20-F) 62 (Feb. 12, 2013), http://annualreports.com/HostedData/AnnualReportArchive/t/NASDAQ_TEVA_2012.pdf.

and belief, Teva Ltd. directs the business practices of Cephalon and Teva USA, and their profits inure to the benefit of Teva Ltd. as controlling shareholder. Teva Pharmaceutical Industries, Ltd., Teva Pharmaceuticals USA, Inc., and Cephalon, Inc. are referred to as "Cephalon."

27. JANSSEN PHARMACEUTICALS, INC. is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey, and is a wholly owned subsidiary of JOHNSON & JOHNSON (J&J), a New Jersey corporation with its principal place of business in New Brunswick, New Jersey. NORAMCO, INC. ("Noramco") is a Delaware company headquartered in Wilmington, Delaware and was a wholly owned subsidiary of J&J until July 2016. ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC., now known as JANSSEN PHARMACEUTICALS, INC., is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey. JANSSEN PHARMACEUTICA INC., now known as JANSSEN PHARMACEUTICALS, INC., is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey. J&J is the only company that owns more than 10% of Janssen Pharmaceuticals' stock and corresponds with the FDA regarding Janssen's products. Upon information and belief, J&J controls the sale and development of Janssen Pharmaceuticals' drugs and Janssen's profits inure to J&J's benefit. (Janssen Pharmaceuticals, Inc., Ortho-McNeil-Janssen Pharmaceuticals, Inc., Janssen Pharmaceutica, Inc., Noramco, and J&J are collectively referred to as "Janssen.")

28. On information and belief, Janssen manufactures, promotes, sells, and distributes drugs in the United States, including the opioid Duragesic (fentanyl). Before 2009, Duragesic accounted for at least $1 billion in annual sales. Until January 2015, Janssen developed, marketed, and sold the opioids Nucynta (tapentadol) and Nucynta ER. Together, Nucynta and Nucynta ER accounted for $172 million in sales in 2014.

29. ENDO HEALTH SOLUTIONS INC. is a Delaware corporation with its principal place of business in Malvern, Pennsylvania. ENDO PHARMACEUTICALS INC. is a wholly owned subsidiary of Endo Health Solutions Inc. and is a Delaware corporation with its principal place of business in Malvern, Pennsylvania. Endo Health Solutions Inc. and Endo Pharmaceuticals Inc. are referred to as "Endo."

30. On information and belief, Endo develops, markets, and sells prescription drugs, including the opioids Opana/Opana ER, Percodan, Percocet, and Zydone, in the United States. Opioids made up roughly $403 million of Endo's overall revenues of $3 billion in 2012. Opana ER yielded $1.15 billion in revenue from 2010 and 2013, and it accounted for 10% of Endo's total revenue in 2012. Endo also manufactures and sells generic opioids such as oxycodone, oxymorphone, hydromorphone, and hydrocodone products in the United States, by itself and through its subsidiary, Qualitest Pharmaceuticals, Inc.

31. ALLERGAN PLC is a public limited company incorporated in Ireland with its principal place of business in Dublin, Ireland. Actavis PLC acquired Allergan PLC in March 2015, and the combined company changed its name to Allergan PLC in June 2015. Before that, WATSON PHARMACEUTICALS, INC. acquired Actavis, Inc. in October 2012, and the combined company changed its name to Actavis, Inc. as of January 2013 and then Actavis PLC in October 2013. WATSON LABORATORIES, INC. is a Nevada corporation with its principal place of business in Corona, California, and is a wholly-owned subsidiary of Allergan PLC (f/k/a Actavis, Inc., f/k/a Watson Pharmaceuticals, Inc.). ACTAVIS PHARMA, INC. (f/k/a Actavis, Inc.) is a Delaware corporation with its principal place of business in New Jersey and was formerly known as WATSON PHARMA, INC. ACTAVIS LLC is a Delaware limited liability company with its principal place of business in Parsippany, New Jersey. Each of these

defendants is owned by Allergan plc, which uses them to market and sell its drugs in the United States. Upon information and belief, Allergan plc exercises control over these marketing and sales efforts and profits from the sale of Allergan/Actavis products ultimately inure to its benefit. (Allergan PLC, Actavis PLC, Actavis, Inc., Actavis LLC, Actavis Pharma, Inc., Watson Pharmaceuticals, Inc., Watson Pharma, Inc., and Watson Laboratories, Inc. are collectively referred to as "Actavis.")

32. On information and belief, Actavis manufactures, promotes, sells, and distributes opioids, including the branded drugs Kadian and Norco, a generic version of Kadian, and generic versions of Duragesic and Opana, in the United States. Actavis acquired the rights to Kadian from King Pharmaceuticals, Inc. on December 30, 2008, and began marketing Kadian in 2009.

33. MALLINCKRODT, PLC is an Irish public limited company headquartered in Staines-upon-Thames, United Kingdom, with its U.S. headquarters in St. Louis, Missouri. MALLINCKRODT, LLC is a limited liability company organized and existing under the laws of the State of Delaware. (Mallinckrodt, LLC is a wholly owned subsidiary of Mallinckrodt, plc. Mallinckrodt, plc and Mallinckrodt, LLC are collectively referred to as "Mallinckrodt.")

34. On information and belief, Mallinckrodt manufactures, markets, and sells drugs in the United States including generic oxycodone, of which it is one of the largest manufacturers. In July 2017 Mallinckrodt agreed to pay $35 million to settle allegations brought by the Department of Justice that it failed to detect and notify the DEA of suspicious orders of controlled substances.

35. INSYS THERAPEUTICS, INC. is a Delaware corporation with its principal place of business in Chandler, Arizona. Insys's principal product and source of revenue is Subsys.

36. On information and belief, Insys made thousands of payments to physicians nationwide, including in Wyoming, ostensibly for activities including participating on speakers' bureaus, providing consulting services, assisting in post-marketing safety surveillance and other services, but in fact to deceptively promote and maximize the use of opioids.

37. Subsys is a transmucosal immediate-release formulation (TIRF) of fentanyl, contained in a single-dose spray device intended for oral, under the tongue administration. Subsys was approved by the FDA solely for the treatment of breakthrough cancer pain.

38. In 2016, Insys made approximately $330 million in net revenue from Subsys. Insys promotes, sells, and distributes Subsys throughout the United States, including Sweetwater County.

39. Insys's founder and owner was recently arrested and charged, along with other Insys executives, with multiple felonies in connection with an alleged conspiracy to bribe practitioners to prescribe Subsys and defraud insurance companies.[15] Other Insys executives and managers were previously indicted.[16]

2. Distributor Defendants

40. The Distributor Defendants also are defined below. At all relevant times, the Distributor Defendants have distributed, supplied, sold, and placed into the stream of commerce the prescription opioids, without fulfilling the fundamental duty of wholesale drug distributors to detect and warn of diversion of dangerous drugs for non-medical purposes. The Distributor Defendants universally failed to comply with federal and/or state law. The Distributor Defendants are engaged in "wholesale distribution," as defined under state and federal law.

[15] Press Release, DOJ, U.S. Attorney's Office, Dist. of Mass., *Founder and Owner of Pharmaceutical Company Insys Arrested and Charged with Racketeering* (Oct. 26, 2017), available at https://www.justice.gov/usao-ma/pr/founder-and-owner-pharmaceutical-company-insys-arrested-and-charged-racketeering.

[16] *Id.*

Plaintiff alleges the unlawful conduct by the Distributor Defendants is responsible for the volume of prescription opioids plaguing Plaintiff's Community.

41. McKESSON CORPORATION ("McKesson") at all relevant times, operated as a registered distributor in Maryland. McKesson is a Delaware corporation. McKesson has its principal place of business located in San Francisco, California.

42. CARDINAL HEALTH, INC. ("Cardinal") at all relevant times, operated as a registered distributor in Maryland. Cardinal's principal office located in Dublin, Ohio. Cardinal operates a distribution center in Baltimore, Maryland.

43. AMERISOURCEBERGEN DRUG CORPORATION ("AmerisourceBergen") at all relevant times, operated as a registered distributor in Maryland. AmerisourceBergen is a Delaware corporation and its principal place of business is located in Chesterbrook, Pennsylvania.

44. Defendant ANDA, INC., ("Anda") through its various DEA registered subsidiaries and affiliated entities, including but not limited to, Anda Pharmaceuticals, Inc., is the fourth largest distributor of generic pharmaceuticals in the United States. Anda is a Florida corporation with its principal office located in Weston, Florida. In October 2016, Defendant Teva acquired Anda from Allergan plc (i.e., Defendant Actavis), for $500 million in cash. At all times relevant to this Complaint, Anda distributed prescription opioids throughout the United States, including in Maryland and Plaintiff's Community specifically. At all relevant times, this Defendant operated as a licensed wholesale distributor in Maryland, licensed by the Maryland Board of Pharmacy.

45. Defendants include the above referenced entities as well as their predecessors, successors, affiliates, subsidiaries, partnerships and divisions to the extent that they are engaged in the manufacture, promotion, distribution sale and/or dispensing of opioids.

III. JURISDICTION AND VENUE

46. This Court has jurisdiction over this action. Defendants are engaging in false and misleading advertising and unlawful, unfair, and deceptive business practices, and creating or assisting in the creation of a public nuisance in Sweetwater County, Wyoming, and the People through their attorneys have the right and authority to prosecute this case on behalf of the People.

47. Jurisdiction of this Court over this action is based upon the diversity of citizenship of the parties pursuant to 28 U.S. Code § 1332(a)(1).

48. The amount of recovery sought herein exceeds the minimum jurisdictional amount required by 28 U.S. Code § 1332(a).

49. Venue is proper in this Court pursuant to 28 U.S. Code § 1332.

IV. FACTUAL ALLEGATIONS

50. Before the 1990s, generally accepted standards of medical practice dictated that opioids should only be used short-term for acute pain, pain relating to recovery from surgery, or for cancer or palliative (end-of-life) care. Due to the lack of evidence that opioids improved patients' ability to overcome pain and function, coupled with evidence of greater pain complaints as patients developed tolerance to opioids over time and the serious risk of addiction and other side effects, the use of opioids for chronic pain was discouraged or prohibited. As a result, doctors generally did not prescribe opioids for chronic pain.

51. To take advantage of the much larger and more lucrative market for chronic pain patients, Defendants had to change this. Each Defendant developed a well-funded marketing and

distribution scheme based on deception. Each Defendant targeted susceptible prescribers and vulnerable patient populations. Each Defendant used both direct marketing and unbranded advertising disseminated by seemingly independent third parties to spread false and misleading statements about the risks and benefits of long-term opioid use. These statements were not only unsupported by or contrary to the scientific evidence, they were also contrary to pronouncements by and guidance from the FDA and the Centers for Disease Control ("CDC") based on that same evidence. Wyoming doctors, including doctors in Sweetwater County and elsewhere in Wyoming, confirm that Defendants began their marketing schemes decades ago and continue them today. And the 2016 CDC Guideline makes it patently clear that their schemes were and continue to be deceptive.

52. The supply chain for prescription opioids begins with the manufacture and packaging of the pills. The manufacturers then transfer the pills to Defendant Distributors for distribution to hospitals, pharmacies, doctors, and other healthcare providers, which then dispense the drugs to patients.

53. Each participant in the supply chain shares the responsibility for controlling the availability of prescription opioids. Opioid "diversion" occurs whenever the supply chain of prescription opioids is broken, and the drugs are transferred from a legitimate channel of distribution or use, to an illegitimate channel of distribution or use. Diversion can occur at any point in the opioid supply chain, including at the pharmacy level when prescriptions are filled for any reason other than a legitimate medical purpose.

54. At the wholesale level of distribution, diversion occurs whenever distributors allow opioids to be lost or stolen in transit, or when distributors fill suspicious orders of opioids from retailers or prescribers. Suspicious orders include orders of unusually large size, orders that

are disproportionately large in comparison to the population of a community served by the pharmacy, orders that deviate from a normal pattern, and or/orders of unusual frequency.

55. Opioid diversion occurs in the United States at an alarming rate. In recent years, the number of people who take prescription opioids for non-medical purposes is greater than the number of people who use cocaine, heroin, hallucinogens, and inhalants combined.

56. Every year, millions of people in the United States misuse and abuse opioid pain relievers that can lead to addiction, overdose and death.

57. Within the last 20 years, the abuse of prescription narcotic pain relievers has emerged as a public health crisis in the United States. Overdose deaths involving prescription opioids have quadrupled since 1999, and so have sales of these prescriptions.

58. In 2011, the CDC reported that overdose deaths from prescription opioids had reached epidemic levels. That year, 16,917 people died from a prescription opioid related overdose, according to the National Institutes of Health. Since then, the death toll has continued to rise. In 2014, 18,893 people died from a prescription opioid related overdose. In 2015, that number increased again to 22,598.

59. In addition, the dramatic rise in heroin use in recent years is a direct result of prescription opioid diversion. The CDC recently reported that the strongest risk factor for a heroin use disorder is prescription opioid use. In one national study covering the period 2008 to 2010, 77.4% of the participants reported using prescription opioids before initiating heroin use. Another study reports that 75% of those who began their opioid abuse in the 2000s started with a prescription opioid. The CDC has reported that people who are dependent on prescription opioid pain killers are 40 times more likely to become dependent on heroin. Heroin deaths are on a

tragic upswing: In 2015, over 12,989 people died from heroin overdose, up more than 20% from approximately 10,574 overdose deaths in 2014.

A. Defendants Targeted Susceptible Prescribers and Vulnerable Patient Populations.

60. As a part of their deceptive marketing scheme, Defendants identified and targeted susceptible prescribers and vulnerable patient populations in the U.S., including Wyoming.

61. For example, Defendants focused their deceptive marketing on primary care doctors, who were more likely to treat chronic paint patients and prescribe them drugs, but were less likely to be schooled in treating pain and the risks and benefits of opioids and therefore more likely to accept Defendants' misrepresentations.

62. Defendants also targeted vulnerable patient populations like the elderly and veterans, who tend to suffer from chronic pain. Defendants targeted these vulnerable patients even though the risks of long-term opioid use were significantly greater for them. For example, the 2016 CDC Guideline observed that existing evidence showed that elderly patients taking opioids suffer from elevated fall and fracture risks, greater risk of hospitalization, and increased vulnerability to adverse drug effects and interactions. The Guideline therefore concluded that there are "special risks of long-term opioid use for elderly patients" and recommended that doctors use "additional caution and increased monitoring" to minimize the risks of opioid use in elderly patients. The same is true for veterans, who are more likely to use anti-anxiety drugs (benzodiazepines) for posttraumatic stress disorder, which interact dangerously with opioids.

B. Defendants Used Multiple Avenues to Disseminate Their False and Misleading Statements about Opioids.

63. To spread their false and misleading statements, Defendants deceptively marketed their branded opioids directly to doctors and patients in Wyoming. Defendants also deployed

seemingly unbiased and independent third parties to spread their false and misleading statements about the risks and benefits of opioids for the treatment of chronic pain throughout Wyoming.

1. Defendants Spread and Continue to Spread Their False and Misleading Statements Through Direct Marketing of Their Branded Opioids.

64. Defendants' direct marketing of opioids generally proceeded on two tracks. First, each Defendant conducted and continues to conduct advertising campaigns touting the purported benefits of their branded drugs. For example, Defendants spent more than $14 million on medical journal advertising of opioids in 2011, nearly triple what they spent in 2001. This amount included $8.3 million by Purdue, $4.9 million by Janssen, and $1.1 million by Endo.

65. A number of Defendants' branded ads deceptively portrayed the benefits of opioids for chronic pain. For example, since at least May 21, 2011, Endo has distributed and made available on its website opana.com a pamphlet promoting Opana ER with photographs depicting patients with physically demanding jobs like construction worker and chef, misleadingly implying that the drug would provide long-term pain-relief and functional improvement. Purdue also ran a series of ads, called "Pain vignettes," for OxyContin in 2012 in medical journals. These ads featured chronic pain patients and recommended OxyContin for each. One ad described a "54-year old writer with osteoarthritis of the hands" and implied that OxyContin would help the writer work more effectively. Endo and Purdue agreed in late 2015 and 2016 to halt these misleading representations in New York, but they may continue to disseminate them in Wyoming.

66. Second, each Defendant promoted the use of opioids for chronic pain through "detailers" — sales representatives who visited individual doctors and medical staff in their offices — and small group speaker programs.

67. These detailers have spread and continue to spread misinformation regarding the risks and benefits of opioids to hundreds of thousands of doctors, including thousands of Wyoming doctors. For example, it is alleged and believed that Defendants' detailers, over the past two years, continue to falsely and misleadingly:

a. Describe the risk of addiction as low or fail to disclose the risk of addiction:

b. Describe their opioid products as "steady state" — falsely implying that these products are less likely to produce the high and lows that fuel addiction — or as less likely to be abused or result in addiction;

c. Tout the effectiveness of screening or monitoring patients as a strategy for managing opioid abuse and addiction;

d. State that there is no maximum close and that doctors can safely increase doses without disclosing the significant risks to patients at higher doses;

e. Discuss "pseudo-addiction";

f. State that patients would not experience withdrawal if they stopped using their opioid products;

g. State that their opioid products are effective for chronic pain without disclosing the lack of evidence for the effectiveness of long-term opioid use; and

h. State that abuse-deterrent formulations are tamper- or crush-resistant and harder to abuse or misuse.

Because these detailers must adhere to scripts and talking points drafted by Defendants, it can be reasonably inferred that most, if not all, of Defendants' detailers made and continue to make these misrepresentations to the thousands of Wyoming doctors they have visited and continue to visit. Defendants have not corrected this misinformation.

68. Defendants[17] also identified doctors to serve, for payment, on their speakers' bureaus and to attend programs with speakers and meals paid for by Defendants. These speaker programs provided: (1) an incentive for doctors to prescribe a particular opioid (so they might be

[17] Upon information and belief, Actavis continued to carry out speaker programs after it acquired Kadian.

selected to promote the drug); (2) recognition and compensation for the doctors selected as speakers; and (3) an opportunity to promote the drug through the speaker to his or her peers. These speakers give the false impression that they are providing unbiased and medically accurate presentations when they are, in fact, presenting a script prepared by Defendants. On information and belief, these presentations conveyed misleading information, omitted material information, and failed to correct Defendants' prior misrepresentations about the risks and benefits of opioids.

69. Each Defendant devoted and continues to devote massive resources to direct sales contacts with doctors. In 2014 alone, Defendants spent $168 million on detailing branded opioids to doctors. This amount is twice as much as Defendants spent on detailing in 2000. The amount includes $108 million spent by Purdue, $34 million by Janssen, $10 million by Endo, and $2 million by Actavis.

70. Defendants' detailing to doctors is effective. Numerous studies indicate that marketing impacts prescribing habits, with face-to-face detailing having the greatest influence. Moreover, more frequent prescribers of opioids in Wyoming are generally more likely to have received a detailing visit. And in some instances, more infrequent prescribers of opioids in Wyoming received a detailing visit from a Defendant's detailer and then prescribed only that Defendant's opioid products.

71. Defendants' detailers have been reprimanded for their deceptive promotions. A July 2010 "Dear Doctor" letter mandated by the FDA required Actavis to acknowledge to the doctors to whom it marketed its drugs that "[b]etween June 2009 and February 2010, Actavis sales representatives distributed ... promotional materials that...omitted and minimized serious risks associated with [Kadian]," including the risk of "[m]isuse, [a]buse, and [d]iversion of [o]pioids" and, specifically, the risk that "[o]pioid[s] have the potential for being abused and are

sought by drug abusers and people with addiction disorders and are subject to criminal diversion."

2. Defendants Used a Diverse Group of Seemingly Independent Third Parties to Spread False and Misleading Statements about the Risks and Benefits of Opioids.

72. Defendants also deceptively marketed opioids in Wyoming through unbranded advertising — i.e., advertising that promotes opioid use generally but does not name a specific opioid. This advertising was ostensibly created and disseminated by independent third parties. But by funding, directing, reviewing, editing, and distributing this unbranded advertising, Defendants controlled the deceptive messages disseminated by these third parties and acted in concert with them to falsely and misleadingly promote opioids for the treatment of chronic pain.[18]

73. Defendants marketed through third-party, unbranded advertising to avoid regulatory scrutiny because that advertising is not submitted to and typically is not reviewed by the FDA. Defendants also used third-party, unbranded advertising to give the false appearance that the deceptive messages came from an independent and objective source. Like tobacco companies, Defendants used third parties that they funded, directed, and controlled to carry out and conceal their scheme to deceive doctors and patients about the risks and benefits of long-term opioid use for chronic pain.

74. Defendants' deceptive unbranded marketing often contradicted what they said in their branded materials reviewed by the FDA. For example, Endo's unbranded advertising contradicted its concurrent, branded advertising for Opana ER:

[18] The phrase "acted in concert" includes conspiring to achieve some end and aiding and abetting in the commission of acts necessary to achieve some end.

Pain: Opioid Therapy (Unbranded)	**Opana ER Advertisement (Branded)**
"People who take opioids **as prescribed usually do not become addicted."**	"All patients treated with opioids require careful monitoring for signs of abuse and addiction, since **use of opioid analgesic products carries the risk of addiction even under appropriate medical use."**

75. Defendants also spoke through a small circle of doctors who, upon information and belief, were selected, funded, and elevated by Defendants because their public positions supported the use of opioids to treat chronic pain. These doctors became known as "key opinion leaders" or "KOLs." Defendants paid these KOLs to serve as consultants or on their advisory boards and to give talks or present continuing medical education programs (CMEs), and their support helped these KOLs become respected industry experts. As they rose to prominence, these KOLs touted the benefits of opioids to treat chronic pain, repaying Defendants by advancing their marketing goals. KOLs' professional reputations became dependent on continuing to promote a pro-opioid message, even in activities that were not directly funded by Defendants.

76. Pro-opioid doctors are one of the most important avenues that Defendants use to spread their false and misleading statements about the risks and benefits of long-term opioid use. Defendants know that doctors rely heavily and more uncritically on their peers for guidance, and KOLs provide the false appearance of unbiased and reliable support for chronic opioid therapy. For example, the New York Attorney General (NY AG) found in its settlement with Purdue that through March 2015 the Purdue website *In the Face of Pain* failed to disclose that doctors who provided testimonials on the site were paid by Purdue and concluded that Purdue's failure to

disclose these financial connections potentially misled consumers regarding the objectivity of the testimonials. KOLs have written, consulted on, edited, and lent their names to books and articles, and given speeches and CMEs supportive of chronic opioid therapy. Defendants created opportunities for KOLs to participate in research studies Defendants suggested or chose and then cited and promoted favorable studies or articles by their KOLs. By contrast, Defendants did not support, acknowledge, or disseminate publications of doctors unsupportive or critical of chronic opioid therapy.

77. Defendants' KOLs also served on committees that developed treatment guidelines that strongly encourage the use of opioids to treat chronic pain and on the boards of pro-opioid advocacy groups and professional societies that develop, select, and present CMEs. These guidelines and CMEs were not supported by the scientific evidence at the time they were created, and they are not supported by the scientific evidence today. Defendants were able to direct and exert control over each of these activities through their KOLs. The 2016 CDC Guideline recognizes that treatment guidelines can "change prescribing practices."

78. Defendants also entered into arrangements with seemingly unbiased and independent patient and professional organizations to promote opioids for the treatment of chronic pain. Under the direction and control of Defendants, these "Front Groups" — which include, but are not limited to, the American Pain Foundation (APF) and the American Academy of Pain Medicine — generated treatment guidelines, unbranded materials, and programs that favored chronic opioid therapy. These guidelines, materials, and programs were not supported by the evidence at the time they were created, and they are not supported by the scientific evidence today. Indeed, they stand in marked contrast to the 2016 CDC Guideline. These Front Groups also assisted Defendants by responding to negative articles, by advocating against regulatory

changes that would limit opioid prescribing in accordance with the scientific evidence, and by conducting outreach to vulnerable patient populations targeted by Defendants.

79. These Front Groups depended on Defendants for funding and, in some cases, for survival. Defendants also exercised control over programs and materials created by these groups by collaborating on, editing, and approving their content, and by funding their dissemination. For example, Purdue's consulting agreement with APF gave it direct, contractual control over APF's work. In doing so, Defendants made sure that the Groups would generate only the messages Defendants wanted to distribute. Despite this, the Front Groups held themselves out as independent and serving the needs of their members — whether patients suffering from pain or doctors treating those patients.

80. Defendants worked together, through Front Groups, to spread their deceptive messages about the risks and benefits of long-term opioid therapy. For example, Defendants combined their efforts through the Pain Care Forum (PCF), which began in 2004 as an APF project. PCF is comprised of representatives from opioid manufacturers (including Endo, Janssen, and Purdue) and various Front Groups, almost all of which received substantial funding from Defendants. Among other projects, PCF worked to ensure that an FDA-mandated education project on opioids was not unacceptably negative and did not require mandatory participation by prescribers, which Defendants determined would reduce prescribing. PCF also worked to address a perceived "lack of coordination" among its members and developed "key" messages that were disseminated in programs and industry-run websites that were available and accessible after May 21, 2011.

C. Defendants' Marketing Scheme Misrepresented the Risks and Benefits of Opioids.

81. To convince doctors and patients in Wyoming that opioids can and should be used to treat chronic pain, Defendants had to convince them that long-term opioid use is both safe and helpful. Knowing that they could do so only by deceiving those doctors and patients about the risks and benefits of long-term opioid use, Defendants made claims that were not supported by or were contrary to the scientific evidence. Even though pronouncements by and guidance from the FDA and the CDC based on that evidence confirm that their claims were false and misleading, the People are informed and believe Defendants have not corrected them and continue to spread them today, including as set forth specifically below.

1. Defendants Falsely Trivialized or Failed to Disclose the Known Risks of Long-Term Opioid Use.

82. To convince doctors and patients that opioids are safe, Defendants deceptively trivialized and failed to disclose the risks of long-term opioid use, particularly the risk of addiction, through a series of misrepresentations that have been conclusively debunked by the FDA and **CDC.** These misrepresentations — which are described below — reinforced each other and created the dangerously misleading impression that: (1) starting patients on opioids was low-risk because most patients would not become addicted, and because those who were at greatest risk of addiction could be readily identified and managed; (2) patients who displayed signs of addiction probably were not addicted and, in any event, could easily be weaned from the drugs; (3) the use of higher opioid doses, which many patients need to sustain pain relief as they develop tolerance to the drugs, do not pose special risks; and (4) abuse-deterrent opioids both prevent abuse and overdose and are inherently less addictive. Defendants have not only failed to correct these misrepresentations, they continue to make them today.

83. First, Defendants falsely claimed that the risk of addiction is low and that addiction is unlikely to develop when opioids are prescribed, as opposed to obtained illicitly; and failed to disclose the greater risk of addiction with prolonged use of opioids. Some illustrative examples of these false and misleading claims that were made by, are continuing to be made by, and/or have not been corrected by Defendants after May 21, 2011 are described below:

a. Actavis's predecessor caused a patient education brochure to be distributed in 2007 that claimed opioid addiction is possible, but "less likely if you have never had an addiction problem." Upon information and belief, based on Actavis's acquisition of its predecessor's marketing materials along with the rights to Kadian, Actavis continued to use this brochure in 2009 and beyond.

b. Purdue and Cephalon sponsored APF's *Treatment Options: A Guide for Living with Pain* (2007), which instructed that addiction is rare and limited to extreme cases of unauthorized dose escalations, obtaining duplicative opioid prescriptions from multiple sources, or theft. This publication is still available online.

c. Endo sponsored a website, Painknowledge.com, which claimed in 2009 that "[p]eople who take opioids as prescribed usually do not become addicted." Another Endo website, PainAction.com, stated "Did you know? Most chronic pain patients do not become addicted to the opioid medications that are prescribed for them." This website was still available online after May 21, 2011.

d. Endo and Cephalon distributed a pamphlet with the Endo logo entitled *Living with Someone with Chronic Pain,* which stated that: "Most health care providers who treat people with pain agree that most people do not develop an addiction problem." A similar statement appeared on the Endo website www.opana.com — which was accessible online after May 21, 2011.

e. Janssen reviewed, edited, approved, and distributed a patient education guide entitled *Finding Relief Pain Management for Older Adults* (2009), which described as "myth" the claim that opioids are addictive, and asserted as fact that "[m]any studies show that opioids are *rarely* addictive when used properly for the management of chronic pain." This guide is still available online.

f. Janssen runs a website, *Prescriberesponsibly.com* (last updated July 2, 2015), which claims that concerns about opioid addiction are "overestimated."

g. Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management* — which claims that less than 1% of children prescribed opioids will become addicted and that pain is undertreated due to "misconceptions about opioid addiction[]." This publication is still available online.

h. Since at least May 21, 2011, detailers for Purdue, Endo, Teva and Janssen in Wyoming have minimized or omitted and continue to minimize or omit any discussion with doctors or their medical staff in Wyoming, including Sweetwater County, about the risk of addiction; misrepresented the potential for abuse of opioids with purportedly abuse-deterrent formulations; and routinely did not correct the misrepresentations noted above.

84. These claims are contrary to longstanding scientific evidence, as the FDA and CDC have conclusively declared. As noted in the 2016 CDC Guideline approved by the FDA, there is "extensive evidence" of the "possible harms of opioids (including opioid use disorder [an alternative term for opioid addiction])." The Guideline points out that "[o]pioid pain medication use presents serious risks, including . . . opioid use disorder" and that "continuing opioid therapy for 3 months substantially increases risk for opioid use disorder." (Emphasis added.)

85. The FDA further exposed the falsity of Defendants' claims about the low risk of addiction when it announced changes to the labels for ER/LA opioids in 2013 and for IR opioids in 2016. In its announcements, the FDA found that "most opioid drugs have 'high potential for abuse' and that opioids "are associated with a substantial risk of misuse, abuse, NOWS [neonatal opioid withdrawal syndrome], addiction, overdose, and death." (Emphasis added.) According to the FDA, because of the "known serious risks" associated with long-term opioid use, including "risks of addiction, abuse, and misuse, even at recommended doses, and because of the greater risks of overdose and death," opioids should be used only "in patients

for whom alternative treatment options" like non-opioid drugs have failed. The FDA further acknowledged that the risk is not limited to patients who seek drugs illicitly; addiction "can occur in patients appropriately prescribed [opioids]."

86. Thus, the warnings on Defendants' own FDA-approved drug labels caution that opioids "expose[] users to risks of addiction, abuse and misuse, which can lead to overdose and death," that the drugs contain "a substance with a high potential for abuse," and that addiction "can occur in patients appropriately prescribed" opioids. (Emphasis added.)

87. The NY AG, in a 2016 settlement agreement with Endo, found that opioid "use disorders appear to be highly prevalent in chronic pain patients treated with opioids, with up to 40% of chronic pain patients treated in specialty and primary care outpatient centers meeting the clinical criteria for an opioid use disorder." Endo had claimed until at least April 2012 on its www.opana.com website that "[m]ost healthcare providers who treat patients with pain agree that patients treated with prolonged opioid medicines usually do not become addicted," but the NY AG found that Endo had no evidence for that statement. Consistent with this, Endo agreed not to "make statements that . . . opioids generally are non-addictive" or "that most patients who take opioids do not become addicted" in New York. Endo remains free, however, to make those statements in Wyoming.

88. Second, Defendants falsely instructed doctors and patients that the signs of addiction are actually signs of undertreated pain and should be treated by prescribing more opioids. Defendants called this phenomenon "pseudoaddiction" — a term coined by Dr. David Haddox, who went to work for Purdue, and popularized by Dr. Russell Portenoy, a KOL for Endo, Janssen, Teva, and Purdue — and falsely claimed that pseudoaddiction is substantiated by scientific evidence. Some illustrative examples of these deceptive claims that were made

by, are continuing to be made by, and/or have not been corrected by Defendants after May 21, 2011 —are described below:

a. Purdue, Cephalon and Endo sponsored *Responsible Opioid Prescribing* (2007), which taught that behaviors such as "requesting drugs by name", "demanding or manipulative behavior," seeing more than one doctor to obtain opioids, and hoarding, are all signs of pseudoaddiction, rather than true addiction. *Responsible Opioid Prescribing* remains for sale online. Endo also distributed this document before and after May 21, 2011.

b. Janssen sponsored, funded, and edited the *Let's Talk Pain* website, which in 2009 stated: "pseudoaddiction . . . refers to patient behaviors that may occur when *pain is under-treated* . . . . Pseudoaddiction is different from true addiction because such behaviors can be resolved with effective pain management." This website was accessible online until May 2012.

c. Endo sponsored a National Initiative on Pain Control (NIPC) CME program in 2009 titled *Chronic Opioid Therapy: Understanding Risk While Maximizing Analgesia,* which promoted pseudoaddiction by teaching that a patient's aberrant behavior was the result of untreated pain. Endo substantially controlled NIPC by funding NIPC projects; developing, specifying, and reviewing content; and distributing NIPC materials. This CME program was still available after May 21, 2011.

d. Purdue published a pamphlet in 2011 entitled *Providing Relief Preventing Abuse,* which described pseudoaddiction as a concept that "emerged in the literature" to describe the inaccurate interpretation of [drug-seeking behaviors] in patients who have pain that has not been effectively treated." This pamphlet was still distributed after May 21, 2011.

e. Purdue sponsored a CME program entitled *Path of the Patient, Managing Chronic Pain in Younger Adults at Risk for Abuse* in 2011. In a role play, a chronic pain patient with a history of drug abuse tells his doctor that he is taking twice as many hydrocodone pills as directed. The narrator notes that because of pseudoaddiction, the doctor should not assume the patient is addicted even if he persistently asks for a specific drug, seems desperate, hoards medicine, or "overindulges in unapproved escalating doses." The doctor treats this patient by prescribing a high-dose, long-acting opioid. This CME program was still available after May 21, 2011.

f. Before and after May 21, 2011, detailers for Purdue have directed doctors and their medical staffs in Wyoming, including Sweetwater County in Wyoming, to PartnersAgainstPain.com, which contained false and misleading materials describing pseudoaddiction.

g. Purdue and Cephalon sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which states: "Pseudo-addiction describes patient behaviors that may occur when *pain is undertreated* . . . Pseudo-addiction can be distinguished from true addiction in that this behavior ceases when pain is effectively treated." (emphasis added.) This publication is still available online.

89. The 2016 CDC Guideline rejects the concept of pseudoaddiction. The Guideline nowhere recommends that opioid dosages be increased if a patient is not experiencing pain relief. To the contrary, the Guideline explains that "[p]atients who do not experience clinically meaningful pain relief early in treatment . . . are unlikely to experience pain relief with longer-term use," and that physicians should "reassess[] pain and function within 1 month" in order to decide whether to "minimize risks of long-term opioid use by discontinuing opioids" because the patient is "not receiving a clear benefit."

90. Even one of the Defendants has effectively repudiated the concept of pseudoaddiction. In finding that "[t]he pseudoaddiction concept has never been empirically validated and in fact has been abandoned by some of its proponents," the NY AG, in its 2016 settlement with Endo, reported that "Endo's Vice President for Pharmacovigilance and Risk Management testified to [the NY AG] that he was not aware of any research validating the `pseudoaddiction' concept" and acknowledged the difficulty in distinguishing "between addiction and `pseudoaddiction.'" Consistent with this, Endo agreed not to "use the term `pseudoaddiction' in any training or marketing" in New York. Endo, however, remains free to do so in Wyoming.

91. Third, Defendants falsely instructed doctors and patients that addiction risk screening tools, patient contracts, urine drug screens, and similar strategies allow them to reliably identify and safely prescribe opioids to patients predisposed to addiction. These misrepresentations were especially insidious because Defendants aimed them at general practitioners and family doctors who lack the time and expertise to closely manage higher-risk

patients on opioids. Defendants' misrepresentations made these doctors feel more comfortable prescribing opioids to their patients, and patients more comfortable starting on opioid therapy for chronic pain. Some illustrative examples of these deceptive claims that were made by, are continuing to be made by, and/or have not been corrected by Defendants after March 21, 2011 are described below:

a. Endo paid for a 2007 supplement in the *Journal of Family Practice* written by a doctor who became a member of Endo's speakers bureau in 2010. The supplement, entitled *Pain Management Dilemmas in Primary Care: Use of Opioids,* emphasized the effectiveness of screening tools, claiming that patients at high risk of addiction could safely receive chronic opioid therapy using a "maximally structured approach" involving toxicology screens and pill counts.

b. Purdue sponsored a November 2011 webinar, *Managing Patient 's Opioid Use: Balancing the Need and Risk,* which claimed that screening tools, urine tests, and patient agreements prevent "overuse of prescriptions" and "overdose deaths."

c. As recently as 2015, Purdue has represented in scientific conferences that "bad apple" patients — and not opioids — are the source of the addiction crisis and that once those "bad apples" are identified, doctors can safely prescribe opioids without causing addiction.

d. Since at least May 21, 2011, detailers for Purdue have touted and continue to tout to doctors in Wyoming, including Sweetwater County in Wyoming, the reliability and effectiveness of screening or monitoring patients as a tool for managing opioid abuse and addiction.

92. Once again, the 2016 CDC Guideline confirms that these statements were false, misleading, and unsupported at the time they were made by Defendants. The Guideline notes that there are no studies assessing the effectiveness of risk mitigation strategies — such as screening tools, patient contracts, urine drug testing, or pill counts widely believed by doctors to detect and deter abuse — "for improving outcomes related to overdose, addiction, abuse, or misuse." As a result, the Guideline recognizes that available risk screening tools "show insufficient accuracy for classification of patients as at low or high risk for [opioid] abuse or misuse" and counsels that

doctors "should not overestimate the ability of these tools to rule out risks from long-term opioid therapy." (Emphasis added.)

93. Fourth, to underplay the risk and impact of addiction and make doctors feel more comfortable starting patients on opioids, Defendants falsely claimed that opioid dependence can easily be addressed by tapering and that opioid withdrawal is not a problem, and failed to disclose the increased difficulty of stopping opioids after long-term use. For example, a 2011 non-credit educational program sponsored by Endo, entitled *Persistent Pain in the Older Adult*, claimed that withdrawal symptoms can be avoided by tapering a patient's opioid dose by 10%--20% for 10 days. Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain and Its Management,* which claimed that "[s]ymptoms of physical dependence can often be ameliorated by gradually decreasing the dose of medication during discontinuation" without mentioning any hardships that might occur. This publication was available on APF's website until the organization dissolved in May 2012. And detailers for Janssen, since at least May 21, 2011 have told and continue to tell doctors in Wyoming, including Sweetwater County, that their patients would not experience withdrawal if they stopped using opioids. Defendants deceptively minimized the significant symptoms of opioid withdrawal – which, as explained the 2016 CDC Guideline, including drug craving, anxiety, insomnia, abdominal pain, vomiting, diarrhea, sweating, tremor, tachycardia (rapid heartbeat), spontaneous abortion and premature labor in pregnant women, and the unmasking of anxiety, depression, and addiction – and grossly understated the difficulty of tapering, particularly after long-term opioid use. Yet the 2016 CDC Guideline recognizes that the duration of opioid use and the dosage of opioids prescribed should be "limit[ed]" to "minimize the need to taper opioids to prevent distressing or unpleasant withdrawal symptoms," because "physical dependence on opioids is an expected physiologic

response in patients exposed to opioids for more than a few days." (Emphasis added.) The Guideline further states that "tapering opioids can be especially challenging after years on high dosages because of physical and psychological dependence" and highlights the difficulties, including the need to carefully identify "a taper slow enough to minimize symptoms and signs of opioid withdrawal" and to "pause[] and restart[]" tapers depending on the patient's response. The CDC also acknowledges that lack of any "high-quality studies comparing the effectiveness of different tapering protocols for use when opioid dosage is reduced, or opioids are discontinued."

94. Numerous Wyoming patients who struggle with opioid addiction, including in Sweetwater County, Wyoming, have found it exceedingly difficult to stop taking prescription opioids due to the extreme withdrawal symptoms. When trying to stop, many addicted individuals become so sick from withdrawal that they begin buying opioids illicitly. Indeed, many begin using heroin to get through the withdrawal symptoms.

95. Fifth, Defendants falsely claimed that doctors and patients could increase opioid dosages indefinitely without added risk and failed to disclose the greater risks to patients at higher dosages. The ability to escalate dosages was critical to Defendants' efforts to market opioids for long-term use to treat chronic pain because, absent this misrepresentation, doctors would have abandoned treatment when patients built up tolerance and lower dosages did not provide pain relief Some illustrative examples of these deceptive claims that were made by, are continuing to be made by, and/or have not been corrected by Defendants after May 21, 2011 are described below:

a. Actavis's predecessor created a patient brochure for Kadian in 2007 that stated, "Over time, your body may become tolerant of your current dose. You may require a dose adjustment to get the right amount of pain relief. This is not addiction." Upon information and belief, based on Actavis's acquisition of its predecessor's marketing materials along with the rights to Kadian, Actavis continued to use these materials in 2009 and beyond.

b. Purdue and Cephalon sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which claims that some patients "need" a larger dose of an opioid, regardless of the dose currently prescribed. The guide stated that opioids have "no ceiling dose" and are therefore the most appropriate treatment for severe pain.[19] This guide is still available for sale online.

c. Endo sponsored a website, painknowledge.com, which claimed in 2009 that opioid dosages may be increased until "you are on the right dose of medication for your pain." The website was still accessible online after May 21, 2011.

d. Endo distributed a pamphlet edited by a KOL entitled *Understanding You• Pain: Taking Oral Opioid Analgesics,* which was still available after May 21, 2011 on Endo's website. In Q&A format, it asked "If I take the opioid now, will it work later when I really need it?" The response is, "The dose can be increased. . . . You won't 'run out' of pain relief"

e. Janssen sponsored a patient education guide entitled *Finding Relief Pain Management for Older Adults* (2009), which was distributed by its sales force. This guide listed dosage limitations as "disadvantages" of other pain medicines but omitted any discussion of risks of increased opioid dosages. This guide is still available online.

f. Through March 2015, Purdue's *In the Face of Pain* website promotes the notion that if a patient's doctor does not prescribe what, in the patient's view, is a sufficient dosage of opioids, he or she should find another doctor who will.

g. Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management,* which taught that dosage escalations are "sometimes necessary," even unlimited ones, but did not disclose the risks from high opioid dosages. This publication is still available online.

h. Purdue sponsored a CME entitled *Overview of Management Options* that is still available for CME credit. The CME was edited by a KOL and taught that NSAIDs and other drugs, but not opioids, are unsafe at high dosages.

i. Purdue presented a 2015 paper at the College on the Problems of Drug Dependence challenging the correlation between opioid dosage and overdose.

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[19] Defendants frequently contrasted the lack of a ceiling dosage for opioids with the risks of a competing class of analgesics: over-the-counter nonsteroidal anti-inflammatories (or NSAIDs). Defendants deceptively describe the risks from NSAIDs while failing to disclose the risks from opioids. *(See e.g., Case Challenges in Pain Management: Opioid Therapy for Chronic Pain* (Endo) (describing massive gastrointestinal bleeds from long-term use of NSAIDs and recommending opioids); *Finding Relief Pain Management for Older Adults* (Janssen) (NSAIDs caused kidney or liver damage and increased risk of heart attack and stroke, versus opioids, which cause temporary "upset stomach or sleepiness" and constipation).)

j. Since at least May 21, 2011, Purdue's detailers have told doctors in Wyoming, including in Wyoming, that they should increase the dose of OxyContin, rather than the frequency of use, to address early failure.

96. These claims conflict with the scientific evidence, as confirmed by the FDA and CDC. As the CDC explains in its 2016 Guideline, the "[b]enefits of high-dose opioids for chronic pain are not established" while the "risks for serious harms related to opioid therapy increase at higher opioid dosage." More specifically, the CDC explains that "there is now an established body of scientific evidence showing that overdose risk is increased at higher opioid doses." The CDC also states that "there is an increased risk for opioid use disorder, respiratory depression, and death at higher dosages." That is why the CDC advises doctors to "avoid increasing dosages" above 90 morphine milligram equivalents per day.

97. The 2016 CDC Guideline reinforces earlier findings announced by the FDA. In 2013, the FDA acknowledged "that the available data do suggest a relationship between increasing opioid dose and risk of certain adverse events." For example, the FDA noted that studies "appear to credibly suggest a positive association between high-dose opioid use and the risk of overdose and/or overdose mortality." In fact, a recent study found that 92% of persons who died from an opioid-related overdose were initially prescribed opioids for chronic pain.

98. Finally, Defendants' deceptive marketing of the so-called abuse-deterrent properties of some of their opioids has created false impressions that these opioids can prevent and curb addiction and abuse. Indeed, in a 2014 survey of 1,000 primary care physicians, nearly half reported that they believed abuse-deterrent formulations are inherently less addictive.

99. These abuse deterrent formulations (AD opioids) are harder to crush, chew, or grind; become gelatinous when combined with a liquid, making them harder to inject; or contain a counteragent such as naloxone that is activated if the tablets are tampered. Despite this, AD

opioids are not "impossible to abuse."[20] They can be defeated — often quickly and easily — by those determined to do so. Moreover, they do not stop oral intake, the most common avenue for opioid misuse and abuse, and do not reduce the rate of misuse and abuse by patients who become addicted after using opioids long-term as prescribed or who escalate their use by taking more pills or higher doses.

100. Because of these significant limitations on AD opioids and because of the heightened risk for misconceptions and for the false belief that AD opioids can be prescribed safely, the FDA has cautioned that "[a]ny communications from the sponsor companies regarding AD properties must be truthful and not misleading (based on a product's labeling), and supported by sound science taking into consideration the totality of the data for the particular drug. Claims for AD opioid products that are false, misleading, and/or insufficiently proven do not serve the public health.[21]

101. Despite this admonition, Defendants have made and continue to make misleading claims about the ability of their so-called abuse-deterrent opioid formulations to prevent or reduce abuse and addiction and the safety of these formulations.

102. For example, Endo has marketed Opana ER as tamper- or crush-resistant and less prone to misuse and abuse since at least May 21, 2011 even though: (1) the FDA rejected Endo's petition to approve Opana ER as abuse-deterrent in 2012; (2) the FDA warned in a 2013 letter that there was no evidence that Opana ER "would provide a reduction in oral, intranasal or intravenous abuse"; and (3) Endo's own studies, which it failed to disclose, showed that Opana ER could still be ground and chewed. Endo's advertisements for the 2012 reformulation of

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[20] FDA Facts: Abuse-Deterrent Opioid Medications, available at: https://www.fda.govinewsevents/newsroom/factsheets/lucm514939.htni [as of July 7, 2017].

[21] *Ibid.*

Opana ER falsely claimed that it was designed to be crush resistant, in a way that suggested it was more difficult to abuse. And since 2012, detailers for Endo have informed Wyoming doctors, including doctors in Sweetwater County, that Opana ER is harder to abuse, and nurse practitioners have reported receiving tamper- and crush-resistant messages regarding Opana ER and demonstrations of Opana ER's purposed abuse deterrent properties.

103. In a 2016 settlement with the NY AG, Endo agreed not to make statements in New York that Opana ER was "designed to be, or is crush resistant." The NY AG found those statements false and misleading because there was no difference in the ability to extract the narcotic from Opana ER. The NY AG also found that Endo failed to disclose its own knowledge of the crushability of redesigned Opana ER in its marketing to formulary committees and pharmacy benefit managers.

104. Because Opana ER could be "readily prepared for injection" and was linked to outbreaks of 1-1IV and a serious blood disease, in May 2017, an FDA advisory committee recommended that Opana ER be withdrawn from the market. The FDA adopted this recommendation on June 8, 2017 and requested that Endo withdraw Opana ER from the market.[22]

105. Likewise, Purdue has engaged and continues to engage in deceptive marketing of its AD opioids — i.e., reformulated Oxycontin and Hysingla — since at least May 21, 2011. Before April 2013, Purdue did not market its opioids based on their abuse deterrent properties. However, numerous Wyoming prescribers report that, beginning in 2013 and continuing today, detailers from Purdue regularly use the so-called abuse deterrent properties of Purdue's opioid products as a primary selling point to differentiate those products from their competitors.

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[22] Press Release, "FDA requests removal of Opana ER for risks related to abuse," June 8, 2017, *available at: https:1 /www .fda.gov/NewsEvents/Newsroom/PressAnnouncements/ticm562401.1itm*

Specifically, these detailers: (1) claim that Purdue's AD opioids prevent tampering and cannot be crushed or snorted; (2) claim that Purdue's AD opioids prevent or reduce opioid misuse, abuse, and diversion, are less likely to yield a euphoric high, and are disfavored by opioid abusers; (3) Purdue's AD opioids are "safer" than other opioids; and (4) fail to disclose that Purdue's AD opioids do not impact oral abuse or misuse and that its abuse deterrent properties can be defeated.

106. These statements and omissions by Purdue are false and misleading and conflict with or are inconsistent with the FDA-approved label for Purdue's AD opioids — which indicates that abusers do seek them because of their high likability when snorted, that their abuse deterrent properties can be defeated, and that they can be abused orally notwithstanding their abuse deterrent properties and which does not indicate that AD opioids prevent or reduce abuse, misuse, or diversion.

107. To the contrary, testimony in litigation against Purdue and other evidence indicates that Purdue knew and should have known that "reformulated OxyContin is not better at tamper resistance than the original OxyContin" and is still regularly tampered with and abused. Websites and message boards used by drug abusers, such as bluelight.org and reddit, also report a variety of ways to tamper with OxyContin and Hysingla, including through grinding, microwaving then freezing, or drinking soda or fruit juice in which the tablet has been dissolved. Even Purdue's own website describes a study it conducted that found continued abuse of OxyContin with so-called abuse deterrent properties. Finally, there are no studies indicating that Purdue's AD opioids are safer than any other opioid products.

108. A 2015 study also shows that many opioid addicts are abusing Purdue's AD opioids through oral intake or by defeating the abuse deterrent mechanism. Indeed, one-third of

the patients in the study defeated the abuse deterrent mechanism and were able to continue inhaling or injecting the drug. And to the extent that the abuse of Purdue's AD opioids was reduced, those addicts simply shifted to other drugs such as heroin.[23] Despite this, J. David Haddox, the Vice President of Health Policy for Purdue, falsely claimed in 2016 that the evidence does not show that Purdue's AD opioids are being abused in large numbers.

109. Similarly, the 2016 CDC Guideline states that "[n]o studies" support the notion that "abuse-deterrent technologies [are] a risk mitigation strategy for deterring or preventing abuse," noting that the technologies "do not prevent opioid abuse through oral intake, the most common route of opioid abuse, and can still be abused by nonoral routes." Tom Frieden, the Director of the CDC, has further reported that his staff could not find "any evidence showing the updated opioids [ADFs] actually reduce rates of addiction, overdoses, or death."[24]

110. These false and misleading claims about the abuse deterrent properties of their opioids are especially troubling. First, Defendants are using these claims in a spurious attempt to rehabilitate their image as responsible opioid manufacturers. Second, these claims are falsely assuaging doctors' concerns about the toll caused by the explosion in opioid prescriptions and use and encouraging doctors to prescribe AD opioids under the mistaken belief that these opioids are safer, even though they are not. Finally, these claims are causing doctors to prescribe more AD opioids -- which are far more expensive than other opioid products even though they provide little or no additional benefit.

111. These numerous, longstanding misrepresentations of the risks of long-term opioid use spread by Defendants successfully convinced doctors and patients to discount those risks.

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[23] Cicero, Theodore J., and Matthew S. Ellis, "Abuse-deterrent formulations and the prescription opioid abuse epidemic in the United States: lessons learned from Oxycontin" (2015) 72.5 *.1/111/IA Psychiatry* 424-430.

[24] Perrone, Drugmakers push profitable, but unproven, opioid solution, 12/15/16.

2. Defendants Grossly Overstated the Benefits of Chronic Opioid Therapy.

112. To convince doctors and patients that opioids should be used to treat chronic pain, Defendants also had to persuade them that there was a significant upside to long-term opioid use. But as the 2016 CDC Guideline makes clear, there is "insufficient evidence to determine the long-term benefits of opioid therapy for chronic pain." (Emphasis added.) In fact, the CDC found that "[n]o evidence shows a long-term benefit of opioids in pain and function versus no opioids for chronic pain with outcomes examined at least 1 year later (with most placebo-controlled randomized trials < 6 weeks in duration)" and that other treatments were more or equally beneficial and less harmful than long-term opioid use. The FDA, too, has recognized the lack of evidence to support long-term opioid use. In 2013, the FDA stated that it was "not aware of adequate and well-controlled studies of opioids use longer than 12 weeks." Despite this, Defendants falsely and misleadingly touted the benefits of long-term opioid use and falsely and misleadingly suggested that these benefits were supported by scientific evidence. Not only have Defendants failed to correct these false and misleading claims, they continue to make them today.

113. For example, Defendants falsely claimed that long-term opioid use improved patients' function and quality of life. Some illustrative examples of these deceptive claims that were made by, are continuing to be made by, and/or have not been corrected by Defendants after May 21, 2011 are described below:

a. Actavis distributed an advertisement that claimed that the use of Kadian to treat chronic pain would allow patients to return to work, relieve "stress on your body and your mental health," and help patients enjoy their lives.

b. Endo distributed advertisements that claimed that the use of Opana ER for chronic pain would allow patients to perform demanding tasks like construction work or work as a chef and portrayed seemingly healthy, unimpaired subjects. These advertisements continued to be distributed after May 21, 2011.

c. Janssen sponsored and edited a patient education guide entitled *Finding Relief Pain Management for Older Adults* (2009) — which states as "a fact" that "opioids may make it *easier* for people to live normally." The guide lists expected functional improvements from opioid use, including sleeping through the night, returning to work, recreation, sex, walking, and climbing stairs and states that "[u]sed properly, opioid medications can make it possible for people with chronic pain to 'return to normal.' This guide was still available after May 21, 2011.

d. Purdue ran a series of advertisements for OxyContin in 2012 in medical journals entitled "Pain vignettes," which were case studies featuring patients with pain conditions persisting over several months and recommending OxyContin for them. The ads implied that OxyContin improves patients' function.

e. *Responsible Opioid Prescribing* (2007), sponsored and distributed by Endo, Cephalon and Purdue, taught that relief of pain by opioids, by itself, improved patients' function. The book remains for sale online.

f. Purdue and Cephalon sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which counseled patients that opioids "give [pain patients] a quality of life we deserve." The guide was available online until APF shut its doors in May 2012.

g. Endo's NIPC website *painknowledge.com* claimed in 2009 that with opioids, "your level of function should improve; you may find you are now able to participate in activities of daily living, such as work and hobbies, that you were not able to enjoy when your pain was worse." Elsewhere, the website touted improved quality of life (as well as "improved function") as benefits of opioid therapy. The grant request that Endo approved for this project specifically indicated NIPC's intent to make misleading claims about function, and Endo closely tracked visits to the site. This website was still accessible online after May 21, 2011.

h. Endo was the sole sponsor, through NIPC, of a series of non-credit educational programs titled Persistent Pain in the Older Patient, which claimed that chronic opioid therapy has been "shown to reduce pain and improve depressive symptoms and cognitive functioning." The CME was disseminated via webcast.

i. Janssen sponsored, funded, and edited a website, Let's Talk Pain, in 2009, which featured an interview edited by Janssen claiming that opioids allowed a patient to "continue to function." This video is still available today on YouTube.

j. Purdue sponsored the development and distribution of APF's A Policymaker's Guide to Understanding Pain & Its Management, which claimed that "multiple

clinical studies" have shown that opioids are effective in improving daily function, psychological health, and health-related quality of life for chronic pain patients." The Policymakers's Guide was originally published in 2011 and is still available online today.

k. In a 2015 video on Forbes.com discussing the introduction of Hysingla ER, Purdue's Vice President of Health Policy, J. David Haddox, talked about the importance of opioids, including Purdue's opioids, to chronic pain patients' "quality of life," and complained that CDC statistics do not take into account that patients could be driven to suicide without pain relief.

l. Since at least May 21, 2011, Purdue's, Endo's, Teva's and Janssen's sales representatives have conveyed and continue to convey to prescribers in Wyoming, including in Wyoming, the message that opioids will improve patient function.

114. These claims find no support in the scientific literature. The FDA and other federal agencies have made this clear for years. Most recently, the 2016 CDC Guideline approved by the FDA concluded that "there is no good evidence that opioids improve pain or function with long-term use, and . . . complete relief of pain is unlikely." (Emphasis added.) The CDC reinforced this conclusion throughout its 2016 Guideline:

- "No evidence shows a long-term benefit of opioids in pain and function versus no opioids for chronic pain with outcomes examined at least 1 year later.
- "Although opioids can reduce pain during short-term use, the clinical evidence review found insufficient evidence to determine whether pain relief is sustained and whether function or quality of life improves with long-term opioid therapy."
- "[E]vidence is limited or insufficient for improved pain or function with long-term use of opioids for several chronic pain conditions for which opioids are commonly prescribed, such as low back pain, headache, and fibromyalgia."

115. The CDC also noted that the risks of addiction and death "can cause distress and inability to fulfill major role obligations." As a matter of common sense (and medical evidence), drugs that can kill patients or commit them to a life of addiction or recovery do not improve their function and quality of life.

116. The 2016 CDC Guideline was not the first time a federal agency repudiated Defendants' claim that opioids improved function and quality of life. In 2010, the FDA warned Actavis, in response to its advertising described above, that "[w]e are not aware of substantial evidence or substantial clinical experience demonstrating that the magnitude of the effect of the drug [Kadian] has in alleviating pain, taken together with any drug-related side effects patients may experience ... results in any overall positive impact on a patient's work, physical and mental functioning, daily activities, or enjoyment of life." And in 2008, the FDA sent a warning letter to an opioid manufacturer, making it publicly made clear "that [the claim that] patients who are treated with the drug experience an improvement in their overall function, social function, and ability to perform daily activities . . . has not been demonstrated by substantial evidence or substantial clinical experience."

117. Defendants also falsely and misleadingly emphasized or exaggerated the risks of competing products like NSAIDs, so that doctors and patients would look to opioids first for the treatment of chronic pain. For example, Defendants, before and after May 21, 2011, have overstated the number of deaths from NSAIDS and have prominently featured the risks of NSAIDS, while minimizing or failing to mention the serious risks of opioids. Once again, these misrepresentations by Defendants contravene pronouncements by and guidance from the FDA and CDC based on the scientific evidence. Indeed, the FDA changed the labels for ER/LA opioids in 2013 and IR opioids in 2016 to state that opioids should only be used as a last resort "in patients for which alternative treatment options" like non-opioid drugs "are inadequate." And the 2016 CDC Guideline states that NSAIDs, not opioids, should be the first-line treatment for chronic pain, particularly arthritis and lower back pain.

118. In addition, since at least May 21, 2011, Purdue has misleadingly promoted OxyContin as being unique among opioids in providing 12 continuous hours of pain relief with one dose. Indeed, Purdue's detailers have, within the last two years, told a doctor in Sweetwater County that OxyContin lasts 12 hours.

119. In fact, OxyContin does not last for 12 hours — a fact that Purdue has known at all times relevant to this action. According to Purdue's own research, OxyContin wears off in under six hours in one quarter of patients and in under 10 hours in more than half. This is because OxyContin tablets release approximately 40% of their active medicine immediately, after which release tapers. This triggers a powerful initial response, but provides little or no pain relief at the end of the dosing period, when less medicine is released. This phenomenon is known as "end of dose" failure, and the FDA found in 2008 that a "substantial number" of chronic pain patients taking OxyContin experience it. This not only renders Purdue's promise of 12 hours of relief false and misleading, it also makes OxyContin more dangerous because the declining pain relief patients experience toward the end of each closing period drives them to take more OxyContin before the next dosing period begins, quickly increasing the amount of drug they are taking and spurring growing dependence.

120. Purdue's competitors were aware of this problem. For example, Endo ran advertisements for Opana ER referring to "real" 12-hour dosing. Nevertheless, Purdue falsely promoted OxyContin as if it were effective for a full 12 hours since at least May 21, 2011. Indeed, at Purdue's instruction, Purdue's sales representatives continue to tell Wyoming doctors that OxyContin lasts a full 12 hours. And if a doctor suggests that OxyContin does not last 12 hours, these sales representatives, at Purdue's instruction, recommend increasing the dose, rather than the frequency of use. Purdue gave its sales representatives these instructions to prevent

doctors from switching, to a different drug and to address the unwillingness of insurers to pay for more frequent use of OxyContin.

D. Defendants Also Engaged in Other Unlawful and Unfair Misconduct.

121. Since at least May 21, 2010, Purdue's sales representatives have pressed doctors to prescribe its opioids in order to be rewarded with talks paid by Purdue.

122. Although the U.S. Drug Enforcement Agency (DEA) has repeatedly informed Purdue about its legal "obligation to design and operate a system to disclose ... suspicious orders of controlled substances" and to inform the DEA "of suspicious orders when discovered," Purdue also unlawfully and unfairly failed to report or address illicit and unlawful prescribing of its drugs after May 21, 2010, despite knowing about it for years. (See 21 C.F.R. § 1301.74(b); 21 U.S.C. § 823(e).)

123. For over a decade, Purdue has been able to track the distribution and prescribing of its opioids down to the retail and prescriber levels. Through its extensive network of sales representatives, Purdue had and continues to have knowledge of the prescribing practices of hundreds of doctors in Wyoming and could identify Wyoming doctors who displayed red flags for diversion such as those whose waiting rooms were overcrowded, whose parking lots had numerous out-of-state vehicles, and whose patients seemed young and healthy or homeless. Using this information, Purdue has maintained a database since 2002 of doctors suspected of inappropriately prescribing its drugs. Rather than report these doctors to state medical boards or law enforcement authorities (as Purdue is legally obligated to do) or cease marketing to them, Purdue used the list to demonstrate the high rate of diversion of OxyContin — the same OxyContin that Purdue had promoted as less addictive — in order to persuade the FDA to bar the manufacture and sale of generic copies of the drug because the drug was too likely to be

abused. In an interview with the Los Angeles Times, Purdue's senior compliance officer acknowledged that in five years of investigating suspicious pharmacies, Purdue failed to take action — even where Purdue employees personally witnessed the diversion of its drugs. The same was true of prescribers; despite its knowledge of illegal prescribing, Purdue did not report until years after law enforcement shut down a Los Angeles clinic that prescribed more than 1.1 million OxyContin tablets and that Purdue's district manager described internally as "an organized drug ring." In doing so, Purdue protected its own profits at the expense of public health and safety.

124. This misconduct by Purdue is ongoing. In 2016, the NY AG found that, between January 1, 2008 and March 7, 2015, Purdue's sales representatives, at various times, failed to timely report suspicious prescribing and continued to detail those prescribers even after they were placed on a "no-call" list.

125. As Dr. Mitchell Katz, director of the Los Angeles County Department of Health Services, said in a Los Angeles Times article, "Any drug company that has information about physicians potentially engaged in illegal prescribing or prescribing that is endangering people's lives has a responsibility to report it." The NY AG's settlement with Purdue specifically cited the company for failing to adequately address suspicious prescribing. Yet, on information and belief, Purdue continues to profit from the prescriptions of such prolific prescribers.

126. Like Purdue, Endo has been cited for its failure to set up an effective system for identifying and reporting suspicious prescribing. In its settlement agreement with Endo, the NY AG found that Endo failed to require sales representatives to report signs of abuse, diversion, and inappropriate prescribing; paid bonuses to sales representatives for detailing prescribers who were subsequently arrested or convicted for illegal prescribing; and failed to prevent sales

representatives from visiting prescribers whose suspicious conduct had caused them to be placed on a no-call list. The NY AG also found that, in certain cases where Endo's sales representatives detailed prescribers who were convicted of illegal prescribing of opioids after May 21, 2011, those representatives could have recognized potential signs of diversion and reported those prescribers but failed to do so.

127. Insys, according to a recent New York Times article, was charged with bribery when it was discovered they bribed doctors to prescribe Subsys (Insys single dose spray under the tongue. It was further discovered that Insys, in an effort to increase prescription (as the cost for Subsys was very high) formed the Insys Reimbursement Center to get approval for reimbursements, and in doing so, employed fraudulent schemes to misrepresent the patient's condition and obtain reimbursement approval.

128. Additionally, Insys was discovered to have incentivized a salesforce by paying bonuses for higher cost drug sales and coordinated a fraudulent speakers program to pay doctors to prescribe Subsys at higher more expensive doses.

129. Indictments and guilty pleas by Insys executives and employees followed. In October, 2017, Insys's founder was charged with bribery.

130. Mallinckrodt marketed several opioid products known as Exalgo, Roxicodone and Xartemis XR. Mallinckrodt promoted these drugs with its own salesforce and would become the leading manufacturer of generic opioid products.

131. In or around 2010 Mallinckrodt started the C.A.R.E.S. (Collaboration and Acting Responsibly to Ensure Safety) Alliance to engage in unbranded marketing for opioids. C.A.R.E.S. promoted a book "Defeat Chronic Pain Now!" minimizing the risk of opioid addiction and emphasizing opioid therapy for regular user for moderate chronic pain.

132. In or around 2013 Mallinckrodt posted a "Mallinckrodt Pharmaceuticals Policy Statement Regarding the Treatment of Pain and Control of Opioid Abuse" on its website minimizing addiction risk and advocating access to opioids. Moreover, Mallinckrodt marketed Exalgo and Xartemis as specially formulated to reduce abuse.

133. In 2017 the DOJ fined Mallinckrodt $35 million for failure to report diversion and faulted recordkeeping. Investigation started in 2011 and reportedly found 44,000 federal violations exposing it to $2.3 billion in fines.

E. Although Defendants Knew That Their Marketing of Opioids Was False and Misleading, They Fraudulently Concealed Their Misconduct.

134. Defendants, both individually and collectively, made, promoted, and profited from their misrepresentations about the risks and benefits of opioids for chronic pain even though they knew that their misrepresentations were false and misleading. The history of opioids, as well as research and clinical experience over the last 20 years, established that opioids were highly addictive and responsible for a long list of very serious adverse outcomes. The FDA and other regulators warned Defendants of this, and Purdue entered into settlements in the hundreds of millions of dollars to address similar misconduct that occurred before 2008. Defendants had access to scientific studies, detailed prescription data, and reports of adverse events, including reports of addiction, hospitalization, and deaths — all of which made clear the harms from long-term opioid use and that patients are suffering from addiction, overdoses, and death in alarming numbers. More recently, the FDA and CDC have issued pronouncements based on the medical evidence that conclusively expose the known falsity of Defendants' misrepresentations, and Endo and Purdue have recently entered agreements prohibiting them from making some of the same misrepresentations described in this Complaint in New York.

135. Moreover, at all times relevant to this Complaint, Defendants took steps to avoid detection of and to fraudulently conceal their deceptive marketing and unlawful, unfair, and fraudulent conduct. For example, Defendants disguised their own role in the deceptive marketing of chronic opioid therapy by funding and working through third parties like Front Groups and KOLs. Defendants purposefully hid behind the assumed credibility of these individuals and organizations and relied on them to vouch for the accuracy and integrity of Defendants' false and misleading statements about the risks and benefits of long-term opioid use for chronic pain.

136. Defendants also never disclosed their role in shaping, editing, and approving the content of information and materials disseminated by these third parties. Defendants exerted considerable influence on these promotional and "educational" materials in emails, correspondence, and meetings with KOLs, Front Groups, and public relations companies that were not, and have not yet become, public. For example, painknowledge.org, which is run by the NIPC, did not disclose Endo's involvement. Other Defendants, such as Purdue and Janssen, ran similar websites that masked their own direct role.

137. Finally, Defendants manipulated their promotional materials and the scientific literature to make it appear that these items were accurate, truthful, and supported by objective evidence when they were not. Defendants distorted the meaning or import of studies they cited and offered them as evidence for propositions the studies did not support. The lack of support for Defendants' deceptive messages was not apparent to medical professionals who relied upon them in making treatment• decisions, nor could it have been detected by the People.

138. Thus, Defendants successfully concealed from the medical community, patients, and health care payors facts sufficient to arouse suspicion of the claims that the People now

assert. The People did not know of the existence or scope of Defendants' industry-wide fraud and could not have acquired such knowledge earlier through the exercise of reasonable diligence.

F. By Knowingly Causing an Explosion in Opioid Prescribing, Use, Misuse, Abuse, and Addiction Through Their Deceptive Marketing Schemes and Unlawful and Unfair Business Practices, Each Defendant Has Created or Assisted in the Creation of a Public Nuisance.

1. Defendants' Deceptive Marketing Scheme Has Caused and Continues to Cause a Huge Increase in Opioid Prescriptions and Use in Wyoming, Including Sweetwater County.

139. Defendants' misrepresentations deceived and continue to deceive doctors and patients in Wyoming, including Sweetwater County, about the risks and benefits of long-term opioid use. Wyoming doctors confirm this. Studies also reveal that many doctors and patients are not aware of or do not understand these risks and benefits. Indeed, patients often report that they were not warned they might become addicted to opioids prescribed to them. As reported in January 2016, a 2015 survey of more than 1,000 opioid patients found that 4 out of 10 were not told opioids were potentially addictive. Indeed, Wyoming residents in treatment for opioid addiction, including residents of Sweetwater County, confirm that they were never told that they might become addicted to opioids when they started taking them, were told that they could easily stop using opioids, or were told that the opioids they were prescribed were less addictive than other opioids.

140. Defendants knew and should have known that their misrepresentations about the risks and benefits of long-term opioid use were false and misleading when they made them.

141. Defendants' deceptive marketing scheme and their unlawful and unfair business practices caused and continue to cause doctors in Wyoming, including doctors in Sweetwater County, to prescribe opioids for chronic pain conditions such as back pain, headaches, arthritis, and fibromyalgia. Absent Defendants' deceptive marketing scheme and their unlawful and unfair

business practices, these doctors would not have prescribed as many opioids to as many patients, and there would not have been as many opioids available for misuse and abuse or as much demand for those opioids.

142. Defendants' deceptive marketing scheme and their unlawful and unfair business practices also caused and continue to cause patients in Wyoming, including patients in Sweetwater County, to purchase and use opioids for their chronic pain believing they are safe and effective. Absent Defendants' deceptive marketing scheme, fewer patients would be using opioids long-term to treat chronic pain, and those patients using opioids would be using less of them. Again, Wyoming doctors and patients confirm this.

143. Defendants' deceptive marketing and their unlawful and unfair business practices have caused and continue to cause the prescribing and use of opioids to explode in Wyoming. including Sweetwater County. Opioids are the most common means of treatment for chronic pain; 20% of office visits now include the prescription of an opioid, and 4 million Americans per year are prescribed a long-acting opioid. This surge in opioid use was not fueled by any scientific developments demonstrating that opioids were safe and effective for previously unaccepted uses; instead, it was fueled by Defendants' desire to sell more drugs.

144. In Wyoming, including Sweetwater County, Defendants' deceptive marketing of the abuse-deterrent properties of their opioids during the past few years has been particularly effective. For example, one survey reports that pain specialists were more likely to recognize that OxyContin had abuse deterrent properties and to prescribe OxyContin specifically because of those properties. Further, prescribers who knew of OxyContin's abuse deterrent properties were using more of it than those who did not know it was an AD opioid. Although sales of AD opioids still represent only a small fraction of opioids sold (less than 5% of all opioids sold in 2015),

they represent a disproportionate share of opioid sales revenue ($2.4 billion or approximately 25% in opioid sales revenue in 2015).

145. The dramatic increase in opioid prescriptions and use corresponds with the dramatic increase in Defendants' spending on their deceptive marketing scheme. Defendants' spending on opioid marketing totaled approximately $91 million in 2000. By 2011, that spending had tripled to $288 million.

2. By Causing an Explosion in Opioid Prescriptions and Use, Defendants Have Created or Assisted in the Creation of a Public Nuisance in Wyoming, Including Sweetwater County.

146. The escalating number of opioid prescriptions written by doctors who were deceived by Defendants' deceptive marketing scheme is the cause of a correspondingly dramatic increase in opioid addiction, overdose, and death throughout the U.S. and Wyoming.

147. Representing the NIFI's National Institute of Drug Abuse in hearings before the Senate Caucus on International Narcotics Control in May 2014, Dr. Nora Volkow explained that "aggressive marketing by pharmaceutical companies" is "likely to have contributed to the severity of the current prescription drug abuse problem."

148. In August 2016, U.S. Surgeon General Vivek Murthy published an open letter to be sent to physicians nationwide, enlisting their help in combating this "urgent health crisis" and linking that crisis to deceptive marketing. He wrote that the push to aggressively treat pain, and the "devastating" results that followed, had "coincided with heavy marketing to doctors . . . . [m]any of [whom] were even taught — incorrectly — that opioids are not addictive when prescribed for legitimate pain."

149. Scientific evidence demonstrates a strong correlation between opioid prescriptions and opioid abuse. In a 2016 report, the CDC explained that "[o]pioid pain reliever prescribing

has quadrupled since 1999 and has increased in parallel with [opioid] overdoses." Patients receiving prescription opioids for chronic pain account for the majority of overdoses. For these reasons, the CDC concluded that efforts to rein in the prescribing of opioids for chronic pain are critical "to reverse the epidemic of opioid drug overdose deaths and prevent opioid-related morbidity."

150. Contrary to Defendants' misrepresentations, most opioid addiction begins with legitimately prescribed opioids. In 2011, 71% of people who abused prescription opioids got them through friends or relatives, not from pill mills, drug dealers or the internet. Numerous doctors and substance abuse counselors in Wyoming note that many of their patients who misuse or abuse opioids started with legitimate prescriptions, confirming the important role that doctors' prescribing habits have played in the opioid epidemic. Treatment centers in Wyoming report that they treat a significant percentage of patients for opioid addiction.

151. The overprescribing of opioids for chronic pain caused by Defendants' deceptive marketing scheme has also resulted in a dramatic rise in the number of infants in Wyoming who are born addicted to opioids due to prenatal exposure and suffer from neonatal abstinence syndrome. These infants face painful withdrawal and may suffer long-term neurologic and cognitive impacts.

152. Opioid addiction is now the primary reason that Wyoming seek substance abuse treatment, and admissions to drug treatment facilities in Wyoming more than doubled from 200607 to 2010-11. Addiction treatment centers indicate that many of their patients started on legal opioid prescriptions.

153. Defendants' creation, through false and misleading advertising and other unlawful and unfair conduct, of a virtually limitless opioid market has significantly harmed communities

in Wyoming, including Sweetwater County. Defendants' success in extending the market for opioids to new patients and chronic pain conditions has created an abundance of drugs available for nonmedical and criminal use and fueled a new wave of addiction and injury. It has been estimated that 60% of the opioids that are abused come, directly or indirectly, through doctors' prescriptions.

154. The rise in opioid addiction caused by Defendants' deceptive marketing scheme has also resulted in an explosion in heroin use. Almost 80% of those who used heroin in the past year previously abused prescription opioids.

155. Many patients who become addicted to opioids will lose their jobs. Some will lose their homes and their families. Some will get treatment, and fewer will successfully complete it; many of those patients will relapse, returning to opioids or some other drug. Of those who continue to take opioids, some will overdose — some fatally, some not. Others will die prematurely from related causes — falling or getting into traffic accidents due to opioid-induced somnolence; dying in their sleep from opioid-induced respiratory depression; suffering assaults while engaging in illicit drug transactions; or dying from opioid-induced heart or neurological disease.

156. Absent each Defendants' deceptive marketing scheme and their unlawful and unfair business practices, the public health crisis caused by opioid misuse, abuse, and addiction in Wyoming, including Sweetwater County, would have been averted or much less severe.

157. These harms in Wyoming, including in Sweetwater County, caused by Defendants' deceptive marketing schemes and unlawful and unfair business practices are a public nuisance because they are "injurious to health" and interfere "with the comfortable enjoyment of

life" and "property" (Civ. Code, § 3479) and because they "affect[] at the same time" "entire communit[ies]" and "neighborhoods" and "any considerable number of persons" (id:, § 3480).

3. Defendants Knew and Should Have Known That Their Deceptive Marketing Schemes Would Create or Assist in the Creation of this Public Nuisance in Sweetwater County.

158. Defendants knew and should have known about these harms that their deceptive marketing and unlawful and unfair business practices have caused and continue to cause in Wyoming, including in Sweetwater County. Defendants closely monitored their sales and the habits of prescribing doctors. Their sales representatives, who visited doctors and attended CMEs, knew which doctors were receiving their messages and how they were responding. Defendants also had access to and watched carefully government and other data that tracked the explosive rise in opioid use, addiction, injury, and death. They knew — and, indeed, intended — that their misrepresentations would persuade doctors in Wyoming, including doctors in Sweetwater County, to prescribe and patients in Wyoming, including patients in Sweetwater County, to use their opioids for chronic pain.

4. Defendants' Conduct and Role in Creating or Assisting in the Creation of the Public Nuisance Is Not Excused by the Actions of any Third Parties and Justifies Greater Civil Penalties.

159. Defendants' actions are not permitted nor excused by the fact that their drug labels may have allowed or did not exclude the use of opioids for chronic pain. FDA approval of opioids for certain uses did not give Defendants license to misrepresent the risks and benefits of opioids. Indeed, Defendants' misrepresentations were directly contrary to pronouncements by and guidance from the FDA based on the medical evidence and their own labels.

160. Nor is Defendants' causal role broken by the involvement of doctors. Defendants' marketing efforts were ubiquitous and highly persuasive. Their deceptive messages tainted

virtually every source doctors could rely on for information and prevented them from making informed treatment decisions. Defendants also were able to harness and hijack what doctors wanted to believe — namely, that opioids represented a means of relieving their patients' suffering and of practicing medicine more compassionately.

161. Finally, each Defendant's conduct and role in creating or assisting in the creation of the public health crisis now plaguing Wyoming and is directly relevant to the amount of the civil penalties being sought herein.

G. Defendants' Fraudulent Marketing Has Led to Record Profits.

162. While the use of opioids has taken an enormous toll on the State of Wyoming and its residents, Defendants have realized blockbuster profits. In 2014 alone, opioids generated $11 billion in revenue for drug companies like Defendants. Indeed, financial information indicates that each Defendant experienced a material increase in sales, revenue, and profits from the false and misleading advertising and other unlawful and unfair conduct described above.

H. Distributor Defendants' Violation of Duty.

163. Distributor Defendants have a duty to exercise reasonable care under the circumstances. This involves a duty not to create a foreseeable risk of harm to others. Additionally, one who engages in affirmative conduct and thereafter realizes or should realize that such conduct has created an unreasonable risk of harm to another is under a duty to exercise reasonable care to prevent the threatened harm.

164. In addition to having common law duties, the Distributor Defendants are governed by the statutory requirements of the Controlled Substances Act ("CSA"), 21 U.S.C. §801 et seq. and its implementing regulations under the FDA. These requirements and regulatory framework were enacted to protect society from the harms of drug diversion. The Distributor

Defendants' violation of these requirements shows that they failed to meet the relevant standard of conduct that society expects from them.

165. The CSA creates a legal regulatory framework for the distribution and dispensing of controlled substances. The CSA acts as a system of checks and balances from the manufacturing level through the delivery of the pharmaceutical drug to the patient or ultimate user. Every person or entity who manufactures, distributes or dispenses opioids must obtain a "registration" with the DEA. Registrants at every level of the supply chain must fulfill their obligations under the CSA, otherwise controlled substances move from the legal to the illicit marketplace, thereby creating. a potential for harm to the general public, including the People of Sweetwater County.

166. All opioid distributors have a duty to maintain effective controls against opioid diversion. They are also required to create and use a system to identify and report downstream suspicious orders of controlled substances to law enforcement. Suspicious orders include orders of unusual size, orders deviating substantially from the normal pattern, and orders of unusual frequency. To comply with these requirements, distributors must know their customers, report suspicious orders, conduct due diligence, and terminate orders if there are indications of diversion.

167. To prevent unauthorized users from obtaining opioids, the CSA creates a distribution monitoring system for controlled substances. At the heart of this system are registration and tracking requirements imposed upon anyone authorized to handle controlled substances. The DEA's Automation of Reports and Consolidation Orders System ("ARCOS") is an automated drug reporting system which monitors the flow of Schedule II controlled substances from their point of manufacture through commercial distribution channels to point of

sale. ARCOS accumulates data on distributors' controlled substances acquisition/distribution transactions, which are then summarized into reports used by the DEA to identify any diversion of controlled substances into illicit channels of distribution. Each person or entity that is registered to distribute ARCOS Reportable controlled substances must report acquisition and distribution transactions to the DEA.

168. Acquisition and distribution transaction reports must provide data on each acquisition to inventory (identifying whether it is, e.g. by purchase or transfer, return from a customer, or supply by the Federal Government) and each reduction from inventory (identifying whether it is, e.g. by sale or transfer, theft, destruction or seizure by Government agencies) for each ARCOS Reportable controlled substance. See 21 U.S.C. § 827(d)(1); 21 C.F.R. §§1304.33(e), (d). Inventory that has been lost or stolen must also be reported separately to the DEA within one business day of discovery of such loss or theft.

169. In addition to filing acquisition/distribution transaction reports, each registrant is required to maintain on a current basis a complete and accurate record of each substance manufactured, imported, received, sold, delivered, exported, or otherwise disposed of. See 21 U.S.C. §§ 827(a)(3), 1304.21(a), 1304.22(b). It is unlawful for any person to negligently fail to abide by the recordkeeping and reporting requirements.

170. In order to maintain registration, distributors must also maintain effective controls against diversion of controlled substances into other than legitimate medical, scientific and industrial channels. When determining if a distributor has provided effective controls, the DEA Administrator refers to the security requirements set forth in §§ 1301.72-1301.76 as standards for the physical security controls and operating procedures necessary to prevent diversion. See 21 CFR § 1301.71.

I. Distributor Defendants Knew or Should Have Known They Were Facilitating Widespread Opioid Diversion.

171. Opioid diversion in the supply chain has always been a widespread problem and has been highly publicized. Numerous publications, studies, federal agencies, Wyoming agencies, and professional health organizations have highlighted the epidemic rate of opioid abuse and overdose rates in communities in Wyoming and Sweetwater County and elsewhere in Wyoming, as well as throughout the United States.

172. To combat the problem of opioid diversion, the DEA has provided guidance to distributors on the requirements of suspicious order reporting in numerous venues, publications, documents, and final agency actions.

173. Since 2006, the DEA has conducted one-on-one briefings with distributors regarding downstream customer sales, their due diligence responsibilities, and their legal and regulatory responsibilities (including the responsibility to know their customers and report suspicious orders to the DEA)). The DEA provided distributors with data on controlled substance distribution patterns and trends, including data on the volume of orders, frequency of orders, and percentage of controlled vs. non-controlled purchases. The distributors were also given case studies, legal findings against other registrants, and ARCOS profiles of their customers whose previous purchases may have reflected suspicious ordering patterns. The DEA pointed out "red flags" distributors should look for in order to identify potential diversion. This initiative was created to help distributors understand their duties with respect to diversion control.

174. Since 2007, the DEA has hosted at least five conferences to provide registrants with updated information about diversion trends and regulatory changes that affect the drug supply chain, the distributor initiative, and suspicious order reporting. All of the major distributors, including McKesson, AmerisourceBergen, and Cardinal Health attended at least one

of these conferences. The conferences allowed the registrants to ask questions and raise concerns. These registrants could also request clarification on DEA policies, procedures, and interpretations of the CSA and implementing regulations.

175. Since 2008, the DEA has participated in numerous meetings and events with the legacy Healthcare Distribution Management Association (FIDMA), now known as the Healthcare Distribution Alliance (HAD), an industry trade association for wholesalers and distributors. DEA representatives have provided guidance to the association concerning suspicious order monitoring, and the association has published guidance documents for its members on suspicious order monitoring, reporting requirements, and the diversion of controlled substances. (1-IDMA, "Industry Compliance Guidelines: Reporting Suspicious Orders and Preventing Diversion of Controlled Substances," (2008).

176. On September 27, 2006 and again on December 27, 2007, the DEA Office of Diversion Control sent letters to all registered distributors providing guidance on suspicious order monitoring of controlled substances and the responsibilities and obligations of the registrant to conduct due diligence on controlled substance customers as part of a program to maintain effective controls against diversion. These letters reminded registrants that they were required by law to exercise due diligence to avoid filling orders that may be diverted into the illicit market. These letters explained that as part of the legal obligation to maintain effective controls against diversion, the distributor is required to exercise due care in confirming the legitimacy of all orders prior to filling.

177. On December 27, 2007, the Office of Diversion Control sent a follow-up letter to DEA registrants providing guidance and reinforcing the legal requirements outlined in the September 2006 correspondence. The December 2007 letter reminded registrants that suspicious

orders must be reported when discovered and monthly transaction reports of excessive purchases did not meet the regulatory criteria for suspicious order reporting. The letter also advised registrants that they must perform an independent analysis of a suspicious order prior to the sale to determine if controlled substances would likely be diverted, and that filing a suspicious order and then completing the sale does not absolve the registrant from legal responsibility.

178. The Distributor Defendants were on notice that their own industry group, the Healthcare Distribution Management Association, published Industry Compliance Guidelines titled "Reporting Suspicious Orders and Preventing Diversion of Controlled Substances" that stressed the critical role of each member of the supply chain in distributing controlled substances.

179. Opioid distributors themselves recognized the magnitude of the problem and, at least rhetorically, their legal responsibilities to prevent diversion. They have made statements assuring the public they are supposedly undertaking a duty to curb the opioid epidemic.

180. For example, a Cardinal executive recently claimed that it uses "advanced analytics" to monitor its supply chain; Cardinal assured the public it was being "as effective and efficient as possible in constantly monitoring, identifying, and eliminating any outside criminal activity."

181. McKesson has publicly stated that it has a "best-in-class controlled substance monitoring program to help identify suspicious orders" and claimed it is "deeply passionate about curbing the opioid epidemic in our country."

182. These assurances, in addition to obligations imposed by law, show that Distributor Defendants understand and have undertaken a duty to protect the public against diversion from their supply chains, and to curb the opioid epidemic.

183. However, despite these statements and duties, Distributor Defendants have knowingly or negligently allowed diversion. Their misconduct has resulted in numerous civil fines and other penalties recovered by state and federal agencies, including actions by the DEA.

184. In 2008, Cardinal Health paid a $34 million penalty to settle allegations about opioid diversion taking place at seven warehouses around the United States. Again in 2012, Cardinal reached an administrative settlement with the DEA relating to opioid diversion between 2009 and 2012 in multiple states. Even very recently, in December 2016, a Department of Justice press release announced that, in connection with CSA violations, the United States reached a $34 million settlement for civil penalties under the CSA. During the investigation of Cardinal, the DEA discovered evidence that Cardinal's own investigator warned Cardinal against selling opioids to a particular pharmacy in Florida that was suspected of opioid diversion. Cardinal took no action and failed to notify the DEA or cut off the supply of drugs to the pharmacy. Instead, Cardinal's opioid shipments to the pharmacy increased to almost 2 million doses of oxycodone in one year, while other comparable pharmacies were receiving approximately 69,000 doses/year.

185. In May 2008, McKesson entered into a settlement agreement with the DEA to settle claims that McKesson failed to maintain effective controls against diversion of controlled substances. McKesson allegedly failed to report suspicious orders from rogue Internet pharmacies around the country, resulting in millions of doses of controlled substances being diverted. McKesson agreed to pay a $13.25 million civil fine. After 2008, McKesson still failed adhere to its duties and it was discovered that in Wyoming, from 2008 to 2013, it filled more than 1.6 million orders, for tens of millions of controlled substances, but it reported just 16 orders as suspicious, all from only a single consumer. Early this year in 2017, it was reported that

McKesson agreed to pay $150 million to the government to settle certain opioid diversion claims that it allowed drug diversion at 12 distribution centers in 11 states.

186. In 2007, AmerisourceBergen lost its license to send controlled substances from a distribution center amid allegations that it was not controlling shipments of prescription opioids to Internet pharmacies. Again in 2012, AmerisourceBergen was implicated for failing to protect against the diversion of particular controlled substances into non-medically necessary channels. It has been reported that the U.S. Department of Justice has subpoenaed AmerisourceBergen for documents in connection with a grand jury proceeding seeking information on the company's "program for controlling and monitoring diversion of controlled substances into channels other than for legitimate medical, scientific and industrial purposes."

187. Although these Distributor Defendants have been penalized by law enforcement authorities, these penalties have not changed their conduct. They pay fines as a cost of doing business in an industry which generates billions of dollars in revenue.

V. CAUSES OF ACTION

FIRST CAUSE OF ACTION
PUBLIC NUISANCE
(Against All Defendants)

188. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth here, and further alleges as follows.

189. The common law of nuisance prohibits persons from endangering the public through actions that affect safety, health, comfort, peace or property of other individuals. See e.g. Restatement (Second) of Torts, § 821B(1). Wyoming law also authorizes local ordinances to prohibit public nuisance. Wyoming Stat. § 35-10-408.

190. Plaintiff and the residents of Plaintiff's Communities have a common right to be free from conduct that creates an unreasonable jeopardy to the public health, welfare and safety, and to be free from conduct that creates a disturbance and reasonable apprehension of danger to person and property.

191. Plaintiff alleges that Defendants have violated their rights by creating a public nuisance through their negligent actions in manufacturing, distributing and promoting opioid medications.

192. Each Defendant is liable for public nuisance because its failure to exercise due care in the manufacture, distribution and promotion of opioid medications has caused an unreasonable interference with a right of the public and specifically the residents of Sweetwater County to enjoy safety, health, comfort, peace or property.

193. In addition, Defendants have acted in an intentional, wrongful or illegal manner such as to create an absolute nuisance.

194. Defendants intentionally, unlawfully, and recklessly manufacture, market, distribute, and sell prescription opioids causing widespread distribution of prescription opioids in and/or to Plaintiff's Communities, resulting in addiction and abuse, an elevated level of crime, death and injuries to the residents of Plaintiff's Communities, a higher level of fear, discomfort and inconvenience to the residents of Plaintiff's Communities with direct costs to Plaintiff's Communities.

195. Defendants have also unlawfully and/or intentionally caused and permitted dangerous drugs under their control to be diverted such as to injure the Plaintiff's Communities and its residents.

196. Defendants have unlawfully and/or intentionally distributed opioids or caused opioids to be distributed without maintaining effective controls against diversion. Defendants' failures to maintain effective controls against diversion include Defendants' failure to effectively monitor for suspicious orders, report suspicious orders, and/or stop shipment of suspicious orders, and constitute intentional and/or unlawful activities.

197. Defendants have caused a significant and unreasonable interference with the public health, safety, welfare, peace, comfort and convenience, and ability to be free from disturbance and reasonable apprehension of danger to person or property.

198. Defendants' conduct in illegally distributing and selling prescription opioids, or causing such opioids to be distributed and sold, where Defendants know, or reasonably should know, such opioids will be diverted and possessed and/or used illegally Plaintiff's Communities is of a continuing nature.

199. Defendants' actions have been of a continuing nature and have produced a significant effect upon the public s rights, including the public s right to health and safety.

200. A violation of any rule or law controlling the distribution of a drug of abuse in Plaintiff's Communities and the State is a public nuisance.

201. Defendants' distribution of opioids while failing to maintain effective controls against diversion was proscribed by statute and regulation.

202. Defendants' ongoing conduct produces an ongoing nuisance, as the prescription opioids that they allow and/or cause to be illegally distributed and possessed in Plaintiff's Communities will be diverted, leading to abuse, addiction, crime, and public health costs.

203. Because of the continued use and addiction caused by these illegally distributed opioids, the public will continue to fear for its health, safety and welfare, and will be subjected to conduct that creates a disturbance and reasonable apprehension of danger to person and property.

204. Defendants know, or reasonably should know, that their conduct will have an ongoing detrimental effect upon the public health, safety and welfare, and the public s ability to be free from disturbance and reasonable apprehension of danger to person and property.

205. Defendants know, or reasonably should know, that their conduct causes an unreasonable invasion of the public right to health, safety and welfare and the public s ability to be free from disturbance and reasonable apprehension of danger to person and property.

206. Defendants' conduct in marketing, distributing, and selling prescription opioids which the defendants know, or reasonably should know, will likely be diverted for non-legitimate, non-medical use, creates a strong likelihood that these illegal distributions of opioids will cause death and injuries to residents in Plaintiff's Communities and otherwise significantly and unreasonably interfere with public health, safety and welfare, and with the public s right to be free from disturbance and reasonable apprehension of danger to person and property.

207. It is, or should be, reasonably foreseeable to Defendants that their conduct will cause deaths and injuries to residents in Plaintiff's Communities, and will otherwise significantly and unreasonably interfere with public health, safety and welfare, and with the public's right to be free from disturbance and reasonable apprehension of danger to person and property.

208. The prevalence and availability of diverted prescription opioids in the hands of irresponsible persons and persons with criminal purposes in Plaintiff's Communities not only causes deaths and injuries, but also creates a palpable climate of fear among residents in

Plaintiff's Communities where opioid diversion, abuse, addiction are prevalent and where diverted opioids tend to be used frequently.

209. Defendants' conduct makes it easier for persons to divert prescription opioids, constituting a dangerous threat to the public.

210. Defendants' actions were, at the least, a substantial factor in opioids becoming widely available and widely used for non-medical purposes. Because of Defendants' special positions within the closed system of opioid distribution, without Defendants' actions, opioid use would not have become so widespread, and the enormous public health hazard of prescription opioid and heroin overuse, abuse, and addiction that now exists would have been averted.

211. The presence of diverted prescription opioids in Plaintiff's Communities, and the consequence of prescription opioids having been diverted in Plaintiff's Communities, proximately results in significant costs to the Plaintiff and to Plaintiff's Communities in order to enforce the law, equip its police force and treat the victims of opioid abuse and addiction.

212. Stemming the flow of illegally distributed prescription opioids, and abating the nuisance caused by the illegal flow of opioids, will help to alleviate this problem, save lives, prevent injuries and make Plaintiff's Communities a safer place to live.

213. Defendants' conduct is a direct and proximate cause of deaths and injuries to the residents of Plaintiff's Communities, costs borne by Plaintiff's Communities and the Plaintiff, and a significant and unreasonable interference with public health, safety and welfare, and with the public's right to be free from disturbance and reasonable apprehension of danger to person and property.

214. Defendants' conduct constitutes a public nuisance and, if unabated, will continue to threaten the health, safety and welfare of the residents of Plaintiff's Communities, creating an

atmosphere of fear and addiction that tears at the residents' sense of well-being and security. Plaintiff has a clearly ascertainable right to abate conduct that perpetuates this nuisance.

215. Defendants created an absolute nuisance. Defendants' actions created and expanded the abuse of opioids, which are dangerously addictive, and the ensuing associated plague of prescription opioid and heroin addiction. Defendants knew the dangers to public health and safety that diversion of opioids would create in Plaintiffs' Communities, however, Defendants intentionally and/or unlawfully failed to maintain effective controls against diversion through proper monitoring, reporting and refusal to fill suspicious orders of opioids. Defendants intentionally and/or unlawfully distributed opioids or caused opioids to be distributed without reporting or refusing to fill suspicious orders or taking other measures to maintain effective controls against diversion. Defendants intentionally and/or unlawfully continued to ship and failed to halt suspicious orders of opioids, or caused such orders to be shipped. Defendants intentionally and/or unlawfully marketed opioids in manners they knew to be false and misleading. Such actions were inherently dangerous.

216. Defendants knew the prescription opioids have a high likelihood of being diverted. It was foreseeable to Defendants that where defendants' distributed prescription opioids or caused such opioids to be distributed without maintaining effective controls against diversion, including monitoring, reporting, and refusing shipment of suspicious orders, that the opioids would be diverted, and create an opioid abuse nuisance in Plaintiff s Communities.

217. Defendants acted with actual malice because Defendants acted with a conscious disregard for the rights and safety of other persons, and said actions have a great probability of causing substantial harm.

218. The damages available to the Plaintiff include, inter alia, recoupment of governmental costs, flowing from an ongoing and persistent public nuisance which the government seeks to abate. Defendants' conduct is ongoing and persistent, and the Plaintiff seeks all damages flowing from Defendants' conduct. Plaintiff further seeks to abate the nuisance and harm created by Defendants' conduct.

219. As a direct result of Defendants' conduct, the Plaintiff and Plaintiff's Communities have suffered actual injury and damages including, but not limited to, significant expenses for police, emergency, health, prosecution, corrections and other services. The Plaintiff here seeks recovery for its own harm.

220. The Plaintiff and Plaintiff's Communities have sustained specific and special injuries because its damages include, inter alia, health services, law enforcement expenditures, and costs related to opioid addiction treatment and overdose prevention.

221. The Plaintiff further seeks to abate the nuisance created by the Defendants' unreasonable, unlawful, intentional, ongoing, continuing, and persistent actions and omissions and interference with a right common to the public.

222. Plaintiff seeks all legal and equitable relief as allowed by law, including *inter alia* abatement, compensatory damages, and punitive damages from the Defendants for the creation of a public nuisance, attorney fees and costs, and pre- and post-judgment interest.

223. Defendants' intentional and unlawful actions and omissions and unreasonable interference with a right common to the public are of a continuing nature.

224. Defendants are aware, and at a bare minimum certainly should be aware, of the unreasonable interference that their conduct has caused in the Plaintiffs Communities. Defendants are in the business of manufacturing or distributing prescription drugs, including

opioids, which are specifically known to Defendants to be dangerous because *inter alia* these drugs are defined under federal and state law as substances posing a high potential for abuse and severe addiction. Defendants created an absolute nuisance. Defendants' actions created and expanded the abuse of opioids, drugs specifically codified as constituting severely harmful substances.

225. The public nuisance created by Defendants' actions is substantial and unreasonable - it has caused and continues to cause significant harm to the Communities, and the harm inflicted outweighs any offsetting benefit. The staggering rates of opioid and heroin use resulting from the Defendants' abdication of their gate-keeping and diversion prevention duties, and the Manufacturer Defendants' fraudulent marketing activities, have caused harm to the entire Communities that includes, but is limited to the high rates of use leading to unnecessary opioid abuse, addiction, overdose, injuries, and deaths.

226. Even children have fallen victim to the opioid epidemic. Easy access to prescription opioids made opioids a recreational drug of choice among teenagers. Even infants have been born addicted to opioids due to prenatal exposure, causing severe withdrawal symptoms and lasting developmental impacts.

227. Even those residents of Plaintiff's Communities who have never taken opioids have suffered from the public nuisance arising from Defendants' abdication of their gate-keeper duties and fraudulent promotions. Many residents have endured both the emotional and financial costs of caring for loved ones addicted to or injured by opioids, and the loss of companionship, wages, or other support from family members who have used, abused, become addicted to, overdosed on, or been killed by opioids.

228. The opioid epidemic has increased health care costs.

229. Employers have lost the value of productive and healthy employees.

230. Defendants' conduct created an abundance of drugs available for criminal use and fueled a new wave of addiction, abuse, and injury.

231. Defendants' violation of duties and/or fraudulent misinformation campaign pushing dangerous drugs resulted in a diverted supply of narcotics to sell, and the ensuing demand of addicts to buy them. More prescription opioids sold by Defendants' led to more addiction, with many addicts turning from prescription opioids to heroin. People addicted to opioids frequently require increasing levels of opioids, and many turned to heroin as a foreseeable result.

232. The diversion of opioids into the secondary, criminal market and the increased number of individuals who abuse or are addicted to opioids increased the demands on health care services and law enforcement.

233. The significant and unreasonable interference with the public rights caused by Defendants' conduct taxed the human, medical, public health, law enforcement, and financial resources of the Plaintiff's Communities.

234. Defendants' interference with the comfortable enjoyment of life in the Plaintiff's Communities is unreasonable because there is little social utility to opioid diversion and abuse, and any potential value is outweighed by the gravity of the harm inflicted by Defendants' actions.

235. The Plaintiff and Plaintiff's Communities have sustained specific and special injuries because its damages include inter alia health services and law enforcement expenditures, as described in this Complaint.

236. Plaintiff seeks economic losses (direct, incidental, and/or consequential pecuniary losses) resulting from the public nuisance created by Defendants' fraudulent activity and

fraudulent misrepresentations. Plaintiff does not seek damages for the wrongful death, physical personal injury, serious emotional distress, or any physical damage to property caused by Defendants' actions.

237. Plaintiff seeks all legal and equitable relief as allowed by law for the public nuisance created by Defendants, other than such damages disavowed herein, including inter alia injunctive relief, restitution, disgorgement of profits, compensatory and punitive damages, and all damages allowed by law to be paid by the Defendants, attorney fees and costs, and pre- and post-judgment interest.

SECOND CAUSE OF ACTION
NEGLIGENCE AND GROSS NEGLIGENCE
(Against all Defendants)

238. Plaintiff realleges and incorporates by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully set forth herein.

239. Defendants had a legal duty to exercise reasonable and ordinary care and skill and in accordance with applicable standards of conduct in advertising, marketing, selling and distributing opioid products in a safe manner to minimize the risk of addiction in patients and resultant harm to those patients, their families and their communities, and to taxpayers and governmental entity such as Plaintiff Sweetwater County which must incur enormous expenditures for prevention, treatment, emergency response and law enforcement costs and other foreseeable costs related to the need to address the consequences of a large number of citizens that become addicted to opioids as a result of Defendants' conduct.

240. Under Wyoming law, Defendants' conduct requires a duty to exercise ordinary care and skill in the in advertising, marketing, selling and distributing opioid products in a safe manner to minimize the risk of addiction in patients and resultant harm to those patients, their

families and their communities, and to taxpayers and governmental entities such as Plaintiff Sweetwater County. Factors in be considered include the following:

a. Foreseeability of harm to Sweetwater County: Defendants were aware or reasonably should have been aware of the risk of addiction of a large number of patients in counties such as Sweetwater County, and need for their care and treatment and in handling other consequences of their addiction and that such costs would be borne by local governments such as Sweetwater County.

b. Degree of certainty Sweetwater County suffered harm: Sweetwater County has suffered enormous harm and costs in addressing treatment of addicted patients, including but not limited to expenditures for prevention, treatment, emergency response and law enforcement costs and other foreseeable costs related to the need to address the consequences of a large number of citizens that become addicted to opioids as a result of Defendants' conduct.

c. Closeness of connection between Defendants' conduct and Sweetwater County's harm: The explosion of opioid addiction and the presence of opioid addicted patients in Sweetwater County as a result of Defendants' conduct has resulted in expenditures directly for prevention, treatment, emergency response and law enforcement costs and other foreseeable costs related to the need to address the consequences.

d. Moral blame attached to Defendants' conduct: Defendants' knew or should have known that their wrongful conduct, actions and omissions would result in an explosion of patients who would become addicted to opioids, and that a vast opioid epidemic would result from the prescription of opioids to tens of millions of patients nationwide, including within Sweetwater County, and that the costs would be borne by the state, county and municipal local governments to, while Defendants profited tens of billions of dollars collectively from the widespread use of prescription opioid products.

e. Policy of preventing future harm: As a direct and foreseeable result of Defendants' wrongful conduct, the opioid epidemic and crisis has and continues to occur on a vast scale both nationally and locally in cities such as Sweetwater County resulting in tremendous harm and cost to the patients, their families and the communities in dealing with this epidemic and crisis, and there is a need to ensure that the costs of such wrongful conduct is borne by Defendants so that parties contemplating such or similar conduct in the future know they will be held responsible for such harm.

f. Extent of burden to Defendants: There is no burden to Defendants in that state and other law precludes them from engaging in the conduct alleged herein, and there is no burden from precluding Defendants from profiting their wrongful conduct and operating within the confines of the law in advertising, marketing, selling and distributing opioid products in a safe manner to minimize the risk of addiction in patients and resultant harm to those patients, their families and their communities, and to taxpayers and municipal government such as Plaintiff Sweetwater County.

241. Defendants breached their duty and were negligent in their actions, misrepresentations, and omissions in numerous ways including but not limited to the conduct and manners alleged herein.

242. Consequences to the Communities of imposing a duty to exercise care with resulting liability for breach: Imposing a duty to exercise not to engage in their wrongful conduct in advertising, marketing, selling and distributing opioid products in a safe manner to minimize the risk of addiction in patients with resulting liability for such breach would benefit communities such as Sweetwater County in that they would not have to incur the foreseeable costs of the opioid epidemic gripping the city and the nation.

243. Defendants advertised, marketed, sold and distributed prescription opioids despite the fact that Defendants knew or should have known of the increased risks associated with using the products, including but not limited to addiction, overdose, death and other adverse effects of which Plaintiff and his healthcare providers would not have been aware.

244. Manufacturer Defendants are guilty of negligence per se in that the Defendants violated the Federal Food, Drug and Cosmetic Act as well as other applicable laws, statutes, and regulations, in the manner in which they advertised, marketed, sold and distributed opioid products.

245. Distributor Defendants are guilty of negligence per se in that the Defendants violated the Federal Food, Drug and Cosmetic Act, Controlled Substances Act "CSA" 21 U.S.C.

§801, et seq., as well as other applicable laws, statutes, and regulations, including but not limited to the following:

a. Distributor Defendants' acts and omissions, including but not limited to Defendants' failure to report inventory that has been lost or stolen as defined by the Federal Food, Drug and Cosmetic Act, CSA 21 U.S.C. §827(d)(1), *et seq* .and 21 C.F.R. §§1304.33(e), (d). Persons such as the People of Sweetwater County were the parties intended to be protected by such legislation and whose injuries said regulations were designed to prevent. Defendants' conduct was a proximate cause of the People of Sweetwater County's injuries.

b. The Defendants' also failed to abide by the recordkeeping and reporting requirements as required by the Federal Food, Drug and Cosmetic Act, CSA 21 U.S.C. §827(a)(3), 1304.21(a), and 1304.22(b), *et seq.* Persons such as the People of Sweetwater County were the parties intended to be protected by such legislation and whose injuries said regulations were designed to prevent. Defendants' conduct was a proximate cause of People of Sweetwater County's injuries.

246. As a direct and proximate consequence of Defendants' negligent, willful, wanton, and intentional acts, omissions, misrepresentations and otherwise culpable acts, there is now a national opioid addiction epidemic, including in the Sweetwater County. As a further direct and proximate consequence and result thereof, Plaintiff has sustained and will continue to sustain injuries and damages including but not limited to tax dollars spent and costs for treatment of opioid addicted patients, emergency response costs, law and regulatory enforcement costs, opioid disposal programs and measures for prevention of further opioid abuse and addiction.

247. Plaintiff seeks economic losses (direct, incidental, or consequential pecuniary losses) resulting from Defendants' fraudulent activity, including fraudulent misrepresentations and fraudulent concealment which has created a substantial and unreasonable risk of death and personal injury in Plaintiff's Communities. Plaintiff does not seek damages for physical personal injury or any physical damage to property caused by Defendants' actions. Plaintiff seeks all legal and equitable relief as allowed by law, except as expressly disavowed herein, including inter alia

injunctive relief, restitution, disgorgement of profits, compensatory and punitive damages, and all damages allowed by law to be paid by the Defendants, attorney fees and costs, and pre- and post-judgment interest.

THIRD CAUSE OF ACTION
NEGLIGENT FAILURE TO WARN
(Against Manufacturer Defendants)

248. Plaintiff incorporates by reference each and every paragraph of this Complaint as though set forth in full in this cause of action and further allege:

249. At all relevant times, the Manufacturer Defendants had a duty to exercise reasonable and ordinary care and skill and in accordance with applicable standards of conduct in adequately warning the medical profession about the risk of addiction from the use of opioid products, and not to overpromote and over-market opioid products so as to nullify, cancel out and render meaningless any written warnings about addiction. however inadequate, about the risk of addiction from the use of opioid products.

250. Defendants breached their duty to exercise reasonable and ordinary care by failing to adequately warn the medical profession about the risk of addiction from the use of opioid products. Moreover, Defendants so overpromoted the products to nullify, cancel out and render meaningless any warnings in the labels about any addiction risk due to Defendants' marketing, sales and promotional efforts that were designed to stimulate the use of opioid products in situations and for patients who should not have been using those drugs or should have used them only as a last resort before other means were used or other less addictive and dangerous drugs were prescribed.

251. As a direct and proximate consequence of Defendants' negligent, willful, wanton, and intentional acts, omissions, misrepresentations and otherwise culpable acts in failing to

adequately warn and overpromoting the use of prescription opioid products, there is now a national opioid addiction epidemic, including in Sweetwater County. As a further direct and proximate consequence and result thereof, Plaintiff has sustained and will continue to sustain, injuries and damages including but not limited to tax dollars spent and costs for treatment of opioid addicted patients, emergency response costs, law and regulatory enforcement costs, opioid disposal programs and measures for prevention of further opioid abuse and addiction.

252. Plaintiff seeks economic losses (direct, incidental, or consequential pecuniary losses) resulting from Defendants' fraudulent activity, including fraudulent misrepresentations and fraudulent concealment which has created a substantial and unreasonable risk of death and personal injury in Plaintiff's Communities. Plaintiff does not seek damages for physical personal injury or any physical damage to property caused by Defendants' actions. Plaintiff seeks all legal and equitable relief as allowed by law, except as expressly disavowed herein, including inter alia injunctive relief, restitution, disgorgement of profits, compensatory and punitive damages, and all damages allowed by law to be paid by the Defendants, attorney fees and costs, and pre- and post-judgment interest.

FOURTH CAUSE OF ACTION
ABNORMALLY DANGEROUS ACTIVITY
(Against All Defendants)

253. Plaintiff realleges and incorporates by referenced paragraphs 1-253 above as if fully set forth herein.

254. Defendants engaged in ultrahazardous or abnormally dangerous activity.

255. Defendants introduced and legitimized the widespread use of highly addictive opioid drugs for treatment of pain even though there was no scientific basis to justify providing that treatment and the known high rate of addiction after limited use.

256. Given the high rate of addiction, the widespread use of opioids to treat chronic pain invites grave harm upon the Communities. The full specter of that harm is clearly evidenced by the opioid epidemic currently ravaging communities across the United States — including Plaintiff's Communities.

257. Before Defendants implemented their marketing scheme to create a demand for their opioid products, the risk of addiction and its terrible life altering effects on event a single patient made doctors reluctant to prescribe opioids. Consequently, opioid painkillers were primarily administered in hospitals and under direct supervision of doctors — most often to cancer or terminally ill patients.

258. Opioids' limited utility and risk of grave harm associated with their use made prescribing rare and unsupervised use nonexistent. Consequently, before Defendants' calculated quest for profits, the use of opioids for medical treatment was extraordinary, exceptional, or unusual.

259. Defendants acted even though they knew that widespread opioid use created a high degree of harm to individual and Communities health and safety. Defendants intended that public use of their opioid products would become widespread in the Communities.

260. Defendants understood that the risk of harm invited by their actions was great: injury or death to the individual addicts, the creation and maintenance of secondary illicit markets for the sale of Defendants products and, when Defendants products are unavailable or too costly, the dramatic increase of secondary illicit markets for heroin and other opiate street drugs.

261. Defendants eroded patient trust in the medical system, made some doctors unwitting drug dealers, and facilitated unscrupulous doctors to use their position and station to turn medical clinics into pill mills — all to the harm of the Communities generally.

262. Defendants' ultrahazardous and abnormally dangerous activities set forth herein caused foreseeable harm to the County and its citizens. The County suffered past economic damages exceeding $750,000.00 and future economic damages exceeding $1,500,000.00.

FIFTH CAUSE OF ACTION
FRAUD AND FRAUDULENT MISREPRESENTATION
(Against All Defendants)

263. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth here, and further alleges as follows.

264. Defendants violated their general duty not to actively deceive, and have made knowingly false statements and have omitted and/or concealed information which made statements by Defendants knowingly false. Defendants acted intentionally and/or unlawfully.

265. Each Defendant owed a duty to the Plaintiff, and to the public in the Plaintiff's Communities, because the injury was foreseeable, and in fact foreseen, by the Defendants.

266. As alleged with specificity above, Defendants made false statements regarding their compliance with state and federal law regarding their duties to prevent diversion, their duties to monitor, report and halt suspicious orders, and/or concealed their noncompliance with these requirements.

267. As alleged with specificity above, the Manufacturer Defendants engaged in false representations and concealments of material fact regarding the use of opioids to treat chronic non-cancer pain.

268. As alleged with specificity above, Defendants knowingly and/or intentionally made representations that were false. Defendants had a duty to disclose material facts and concealed them. These false representations and concealed facts were material to the conduct and actions at issue. Defendants made these false representations and concealed facts with knowledge of the falsity of their representations, and did so with the intent of misleading Plaintiff, Plaintiff's Communities, the public, and persons on whom Plaintiff relied.

269. These false representations and concealments were reasonably calculated to deceive Plaintiff, Plaintiff's Communities, and the physicians who prescribed opioids for persons in Plaintiff's Communities, were made with the intent to deceive, and did in fact deceive these persons, Plaintiff, and Plaintiff's Communities.

270. Plaintiff, Plaintiff's Communities, and the physicians who prescribed opioids reasonably relied on these false representations and concealments of material fact.

271. Plaintiff justifiably relied on Defendants' representations and/or concealments, both directly and indirectly. Plaintiff's injuries were proximately caused by this reliance.

272. The injuries alleged by Plaintiff herein were sustained as a direct and proximate cause of Defendants' fraudulent conduct.

SIXTH CAUSE OF ACTION
CONSTRUCTIVE FRAUD
(Against All Defendants)

273. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein, and further alleges as follows.

274. Under Wyoming law, constructive fraud has been defined as consisting of all acts, omissions, and concealments involving breaches of a legal or equitable duty resulting in damage

to another, and exists where such conduct, although not actually fraudulent, ought to be so treated when it has the same consequence and legal effects.

275. Defendants owed a legal or equitable duty to the Plaintiff and Plaintiff's Communities to provide accurate information to Plaintiff and Plaintiff's Communities. Defendants gained the confidence of Plaintiff and Plaintiff's Communities, and purported to act and inform Plaintiff and Plaintiff's Communities with the interests of people in Plaintiff's Communities in mind.

276. Plaintiff and Plaintiff's Communities put their trust in Defendants to provide accurate information and were influenced by the information provided.

277. Defendants breached their duty to provide accurate information by making false statements and omitting and/or concealing information.

278. As alleged with specificity above, Defendants made false statements regarding their compliance with state and federal law regarding their duties to prevent diversion, their duties to monitor, report and halt suspicious orders, and/or concealed their noncompliance with these requirements.

279. As alleged with specificity above, the Manufacturer Defendants engaged in false representations and concealments of material fact regarding the use of opioids to treat chronic non-cancer pain.

280. Defendants had a duty to disclose material facts and concealed them. These false representations and concealed facts were material to the conduct and actions at issue.

281. These false representations and concealments had a tendency to deceive Plaintiff, Plaintiff's Communities, and the physicians who prescribed opioids for persons in Plaintiff's Communities, and did in fact deceive these persons, Plaintiff, and Plaintiff's Communities.

282. These false representations and concealments injured the public interest.

283. Plaintiff, Plaintiff's Communities, and the physicians who prescribed were influenced by these false representations and concealments of material fact.

284. The failure of Defendants to provide accurate information about suspicious orders and the dangers of opioids amounts to constructive fraud under Maryland law.

285. The injuries alleged by Plaintiff herein were sustained as a direct and proximate cause of Defendants' constructive fraud.

286. Plaintiff seeks economic losses (direct, incidental, or consequential pecuniary losses) resulting from Defendants' constructive fraud which has created a substantial and unreasonable risk of death and personal injury in Plaintiff's Communities. Plaintiff does not seek damages for physical personal injury or any physical damage to property caused by Defendants' actions.

287. Plaintiff seeks all legal and equitable relief as allowed by law, except as expressly disavowed herein, including inter alia injunctive relief, restitution, disgorgement of profits, compensatory and punitive damages, and all damages allowed by law to be paid by the Defendants, attorney fees and costs, and pre- and post-judgment interest.

SEVENTH CAUSE OF ACTION
RACKETEER-INFLUENCED AND CORRUPT ORGANIZATIONS ACT
18 U.S.C. §1961 *et seq.*
(Against all Defendants)

288. Plaintiff incorporates by reference all preceding paragraphs of this Complaint as if fully set forth herein and further alleges as follows.

289. Defendants conducted and continue to conduct their business through legitimate and illegitimate means in the form of an association-in-fact enterprise and/or a legal entity enterprise. At all relevant times, Defendants were each a "person" under 18 U.S.C. § 1961(3)

because they are entities capable of holding, and do hold, a legal or beneficial interest in property.

290. For over a decade, the Defendants aggressively sought to bolster their revenue, increase profit, and grow their share of the prescription painkiller market by unlawfully and surreptitiously increasing the volume of opioids they sold. However, the Defendants are not permitted to engage in a limitless expansion of their market through the unlawful sales of regulated painkillers. As "registrants," the Defendants operated and continue to operate within the closed system created by the CSA. The CSA restricts the Defendants' ability to manufacture or distribute Schedule II controlled substances like opioids by requiring Defendants to maintain effective controls against diversion, design and operate a system to identify suspicious orders and halt such unlawful sales and report them to the DEA, and to make sales within a limited quota set by the DEA.

291. The closed system created by the CSA, including the establishment of quotas, was specifically intended to reduce or eliminate the diversion of Schedule II controlled substances, including opioids.

292. Finding it impossible to achieve their increasing sales ambitions through legal means, the Defendants systematically and fraudulently violated their statutory duties to maintain effective controls against diversion of their drugs, to design and operate a system to identify suspicious orders of their drugs, to halt unlawful sales of suspicious orders and to notify the DEA of suspicious orders. The Defendants repeatedly engaged in unlawful sales of painkillers, which, in turn, artificially and illegally increased the annual production quotas for opioids allowed by the DEA.

293. An association-in-fact enterprise between the Distributor Defendants and the Pharmaceutical Defendants hatched this illegal scheme, and each Defendant participated in the scheme's execution, the purpose of which was to engage in the unlawful sale of opioids while deceiving the public and regulators into believing that the Defendants were faithfully fulfilling their obligations. As a direct result of the Defendants' scheme, they were able to extract billions of dollars in revenue while entities like the Tribe experienced millions of dollars in injuries caused by the foreseeable--and inevitable--consequences of the opioid epidemic Defendants created.

294. Alternatively, Defendants were also members of a legal entity enterprise. The Healthcare Distribution Alliance ("HDA")[25] is a distinct legal entity that qualifies as an enterprise under 18 U.S.C. § 1961(4). On information and belief, each Defendant is a member, participant, and/or sponsor of the HDA. Defendants utilized the HDA to conduct the RICO Enterprise. Each of the Defendants is a legal entity separate from the HDA.

295. The RICO Enterprise: Congress enacted the CSA to create a closed system for distribution of controlled substances. Congress was concerned with the diversion of drugs out of legitimate channels of distribution. Moreover, Congress specifically designed the closed system to ensure that there are multiple ways of identifying and preventing diversion.

296. A central component of the closed system was Congress's directive that the DEA determine quotas of each basic class of Schedule I and Schedule II controlled substances each year.

297. The Defendants operated as an association-in-fact to unlawfully increase sales and revenues in order to unlawfully increase the quotas set by the DEA, which in turn allowed them

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[25] Health Distribution Alliance, *History,* Health Distribution Alliance, https://www.healthcaredistribution.org/about/hda-history (last accessed March 15, 2018).

to collectively profit from distributing a greater pool of opioids each year. Each member of the Rico Enterprise participated in the conduct of the enterprise, including patterns of racketeering activity, and shared in the astounding profits generated by the scheme.

298. The Defendants also engaged in lobbying efforts against the DEA's authority to investigate and hold responsible those who failed in their duty to prevent diversion. The Ensuring Patient Access and Effective Drug Enforcement Act was the result of an effort by the Defendants to reduce the DEA's ability to issue orders to show cause and to suspend and/or revoke registrations. On information and belief, the Pain Care Forum and its members poured millions of dollars into lobbying efforts while the FDA devoted over a million dollars a year to lobbying.

299. The RICO Enterprise functioned by selling prescription opioids in interstate commerce in violation of the Defendants' legal obligations to maintain effective controls against opioid diversion.

300. Each Defendant communicated with other Defendants, shared information on a regular basis, and participated in joint lobbying efforts, trade industry organizations, contractual relationships, and other coordination of activities to effect the RICO Scheme. The contractual relationships included, on information and belief, rebates and/or chargebacks on opioid sales and security arrangements. On information and belief, from 2006 to 2015, the Defendants worked together through the Pain Care Forum to spend over $740 million in lobbying across the country to enable the RICO Enterprise.[26]

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[26] *See* Matthew Perrone, *Pro-Painkiller echo chamber shaped policy amid drug epidemic,* The Center for Public Integrity, https://wwvv.publicintegrity.org/2016/09/19/20201/pro-painkiller-echo-chamber-shaped-policy-amid-drug-epidemic (last accessed March 30, 2018).

301. The Defendants disseminated false and misleading statements to the public regarding the safety of prescription opioids for chronic pain relief. The Defendants also falsely disseminated statements that they were complying with their obligations to maintain effective controls against the diversion of their prescription opioids.

302. The Defendants refused to identify, investigate, or report suspicious orders despite their actual knowledge of drug diversion rings.

303. The Defendants worked together to ensure that opioid production quotas continued to increase, allowing them to generate more and more profits from the RICO Enterprise.

304. The RICO Scheme: Participants took intentional and affirmative steps to conceal the Scheme, including by using unbranded advertisement, third parties, and the Front Groups to disguise the source of the participants' fraudulent statements and to increase the effectiveness of the participants' misinformation campaign. These actions were taken to ensure that the RICO Scheme continued to be effective.

305. The pattern of racketeering activity: Each time that a participant in the RICO Scheme distributed a false statement by mail or wire, it committed a separate act of mail fraud or wire fraud under 18 U.S.C. §§ 1341 and 1341, respectively.

306. The Defendants used, or caused to be used, thousands of interstate mail and wire communications through virtually uniform misrepresentations, concealments, and material omissions regarding the safety of opioids and their compliance with the CSA's anti-diversion requirements. The Defendants committed this continuous pattern of racketeering activity intentionally and knowingly with the intent to advance the RICO Enterprise.

307. The Defendants also conducted a pattern of racketeering by the felonious manufacture, importation, receiving, concealment, buying, selling or otherwise dealing in a controlled substance punishable under any law of the United States. Specifically, 21 U.S.C. § 483(a)(4) makes it unlawful for any person to knowingly or intentionally furnish false information or omit any material information from any application, report, record or other document required to be made, kept, or filed, a violation of which is a felony.

308. Each of the Defendants was a registrant under the CSA and was required to maintain effective diversion controls and investigate and report suspicious orders.

309. The Defendants knowingly and routinely furnished false, misleading, or incomplete information in their reports to the DEA and in their applications for production quotas. As described herein, the Defendants did unlawfully, knowingly, and intentionally conspire, confederate, and agree with each other to engage in the scheme described herein, in violation of 18 U.S.C. § 1962(c) and (d).

310. As a result of the conduct by the Defendants, Plaintiff has been and continues to be injured in an amount to be determined in this litigation.

311. Pursuant to 18 U.S.C. § 1964(c), Plaintiff is entitled to recover threefold its damages, costs, and attorney's fees. In addition, the Tribe is entitled to injunctive relief to enjoin the racketeering activity.

EIGHTH CAUSE OF ACTION
DECEPTIVE TRADE PRACTICES
(Against All Defendants)

312. Plaintiff incorporates by reference all preceding paragraphs of this Complaint as if fully set forth herein and further alleges as follows.

313. The Defendants knowingly used or employed—and continue to use and employ—a deceptive act or practice, fraud, false pretense, false promises, or misrepresentation to conceal, suppress, or omit any material fact in connection with the sale or advertisement of prescription opioids, as more fully described in this Complaint, in violation of applicable law.

314. The Pharmaceutical Defendants' violations directly and proximately caused Plaintiff to suffer economic damages in an amount to be determined in this litigation.

NINTH CAUSE OF ACTION
NEGLIGENCE PER SE
(Against all Defendants)

315. The Tribe incorporates by reference all preceding paragraphs of this Complaint as if fully set forth herein and further alleges as follows.

316. All Defendants had a duty under the CSA and its implementing regulations to prevent the diversion of prescription opioids.

317. The CSA and its implementing regulations were enacted to promote safety and to prevent exactly the type of harm that occurred as a result of Defendants' failures.

318. Further, under the Federal Food, Drug, and Cosmetic Act ("the FDCA"), all Defendants had a duty to prevent the introduction or delivery into interstate commerce of any drug that is adulterated or misbranded. 21 USC § 331(a).

319. Drug advertising is considered misbranded if any statement of fact (or omission of information) is misleading as to a material issue. 21 USC § 321(n). The FDA further requires that all drug advertisements contain balanced, truthful, and scientifically supported statements of fact. 21 C.F.R. § 202.1. It is a violation of FDA regulations to fail to reveal facts that are material in light of other representations made or suggested, and with respect to the consequences that may result from the use of the drug. 21 C.F.R. § 1.21.

320. The FDCA and these FDA regulations were enacted to promote safety and to prevent exactly the type of harm that occurred as a result of Defendants' failures.

321. All Defendants engaged in misrepresentation and fraud, and aided and abetted the use of misrepresentation and fraud, in the distribution of prescription opioids in Wyoming and the Plaintiff's Communities.

322. Further, as alleged in this Complaint, Defendants misbranded their drugs by providing false, misleading, and/or incomplete information about the risks and benefits of their products.

323. As such, all Defendants failed to perform their statutory and regulatory duties under the CSA, FDCA, and other applicable laws and regulations.

324. Defendants' breach of these duties of care foreseeably and proximately caused damage to Plaintiff.

325. Plaintiff is entitled to recover damages from Defendants in an amount to be determined in this litigation.

TENTH CAUSE OF ACTION
CIVIL CONSPIRACY
(Against All Defendants)

326. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein, and further alleges as follows.

327. Defendants engaged in a civil conspiracy to create a public nuisance in conjunction with their unlawful marketing, sale, distribution and/or diversion of opioids into the State and Plaintiff's Communities.

328. Defendants engaged in a civil conspiracy to commit fraud and misrepresentation in conjunction with their unlawful distribution and diversion of opioids into Wyoming and Plaintiff's Communities.

329. Distributor and Manufacturer Defendants unlawfully failed to act to prevent diversion and failed to monitor for, report, and prevent suspicious orders of opioids.

330. The Manufacturer Defendants further unlawfully marketed opioids in Wyoming and Plaintiff's Communities in furtherance of that conspiracy.

331. Defendants acted tortuously in agreement and/or in concert with each other and/or in pursuit of a common design, and/or Defendants knew each other's conduct constituted a breach of their legal duties and provided substantial assistance and/or encouragement in the conduct.

332. Defendants' conspiracy is a continuing conspiracy, and the overt acts performed in compliance with the conspiracy's objective(s) are ongoing and/or have occurred within the last year.

333. Defendants' conspiracy and acts in furtherance thereof are alleged in greater detail earlier in the complaint, including, without limitation, in Plaintiff's RICO allegations above. Said allegations are incorporated herein.

334. Defendants acted with agreement and a common understanding or design to commit unlawful acts and/or lawful acts unlawfully, as alleged herein, and acted purposely, without a reasonable or lawful excuse, to create the injuries alleged herein.

335. Defendants acted with malice, purposely, intentionally, unlawfully, and without a reasonably or lawful excuse.

336. Defendants' conspiracy, and Defendants' actions and omissions in furtherance thereof, proximately caused and/or substantially contributed to the direct and foreseeable losses alleged herein.

337. Plaintiff seeks economic losses (direct, incidental, or consequential pecuniary losses) resulting from Defendants' civil conspiracy. Plaintiff does not seek damages for physical personal injury or any physical damage to property caused by Defendants' actions.

338. Plaintiff seeks all legal and equitable relief as allowed by law, except as expressly disavowed herein, including inter alia injunctive relief, restitution, disgorgement of profits, compensatory and punitive damages, and all damages allowed by law to be paid by the Distributor Defendants, attorney fees and costs, and pre- and post-judgment interest.

ELEVENTH CAUSE OF ACTION
UNJUST ENRICHMENT
(Against All Defendants)

339. Plaintiff incorporates all paragraphs of this Complaint as if set forth fully herein, and further allege as follows.

340. Defendants have unjustly retained a benefit to Plaintiff's detriment, and the Defendants' retention of the benefit violates the fundamental principles of justice, equity, and good conscience.

341. As an expected and intended result of their knowing and intentional wrongdoing as set forth above, Defendants have profited and benefited from the increase in the distribution and purchase of opioids within Plaintiff's Communities, including from opioids foreseeably and deliberately diverted within and into Plaintiff's Communities.

342. Unjust enrichment arises not only where an expenditure by one party adds to the property of another, but also where the expenditure saves the other from expense or loss.

343. Plaintiff has expended substantial amounts of money in an effort to remedy or mitigate the societal harms caused by Defendants' conduct.

344. These expenditures include the provision of healthcare services and treatment services to people who use opioids.

345. These expenditures have helped sustain Defendants' exceedingly profitable businesses.

346. Plaintiff has conferred a benefit upon Defendants by paying for the harms caused by Defendants' improper distribution practices.

347. Defendants were aware of these obvious benefits, and their retention of the benefit is unjust.

348. Defendants have unjustly benefited from Plaintiff's payments because they allowed Defendants to continue providing customers with a high volume of opioid products. The cost of Defendants' wrongful conduct in selling and distributing opioids includes, *inter alia*, increased healthcare services and addiction treatment for opioid users. These costs borne by Plaintiff are not part of the normal and expected costs of a local government's existence. By using Plaintiff to fund the cost of the harms caused by Defendants' wrongful practices, Defendants knowingly saved on expenses, thereby allowing them to sell and distribute more opioids, and make even more money. Defendants have thereby received a benefit unjustly financed by the Plaintiff.

349. Because of their deceptive marketing of prescription opioids, Manufacturer Defendants received unjust enrichment they would not otherwise have obtained. Because of their conscious failure to exercise due diligence in preventing diversion, Defendants obtained

enrichment they would not otherwise have obtained. The enrichment was without justification and Plaintiff lacks a remedy provided by law.

350. Defendants have unjustly retained benefits to the detriment of Plaintiff, and Defendants' retention of such benefits violates the fundamental principles of justice, equity, and good conscience.

351. Defendants' misconduct alleged in this case is ongoing and persistent.

352. Defendants' misconduct alleged in this case does not concern a discrete event or discrete emergency of the sort the Plaintiff would reasonably expect to occur, and is not part of the normal and expected costs of a local government's existence. Plaintiff alleges wrongful acts which are neither discrete nor of the sort a local government can reasonably expect.

353. Plaintiff has incurred expenditures for special programs over and above its ordinary public services.

354. In addition, Plaintiff has made payments for opioid prescriptions, and Defendants benefitted from those payments. Because of their deceptive promotion of opioids, Defendants obtained enrichment they would not otherwise have obtained. The enrichment was without justification and Plaintiff lacks a remedy provided by law.

355. As a direct and proximate result of Defendants' unlawful acts, Plaintiff has been damaged and continues to be damaged, in a substantial amount to be determined at trial.

356. Plaintiff seeks an order compelling Defendants to disgorge all unjust enrichment to Plaintiff; and awarding such other, further, and different relief as this Honorable Court may deem just.

WHEREFORE, Plaintiff respectfully prays for judgment against Defendants and seeks compensatory, exemplary and punitive damages, together with interest, the costs of suit and attorneys' fees, and such other and further relief as this Court deems just and proper.

JURY DEMAND

Plaintiff hereby requests a jury trial in this matter.

DATED this 11th day of January, 2019.

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